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Presidential Documents

Title 3—

The President

Executive Order 13537 of April 14, 2010

Interagency Group on Insular Areas

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

Section 1. *Interagency Group on Insular Areas.*

(a) There is established, within the Department of the Interior for administrative purposes, the Interagency Group on Insular Areas (IGIA) to address policies concerning Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands (Insular Areas).

(b) The IGIA shall consist of:

(i) the heads of the executive departments, as defined in 5 U.S.C. 101;

(ii) the heads of such other executive agencies as the Co-Chairs of the IGIA may designate; and (iii) the Deputy Assistant to the President and Director of Intergovernmental Affairs.

(c) The Secretary of the Interior and the Deputy Assistant to the President and Director of Intergovernmental Affairs shall serve as Co-Chairs of the IGIA, convene and preside at its meetings, direct its work, and establish such subgroups of the IGIA as they deem appropriate, consisting exclusively of members of the IGIA.

(d) Members of the IGIA may designate a senior department or agency official who is a full-time officer or employee of the Federal Government to perform their IGIA functions.

Sec. 2. *Functions of the IGIA.* The IGIA shall:

(a) advise the President on establishment or implementation of policies concerning the Insular Areas;

(b) solicit information and advice concerning the Insular Areas from the Governors of, and other elected officials in, the Insular Areas (including through at least one meeting each year with any Governors of the Insular Areas who may wish to attend) in a manner that seeks their individual advice and does not involve collective judgment, or consensus advice or deliberation;

(c) solicit information and advice concerning the Insular Areas, as the IGIA determines appropriate, from representatives of entities or other individuals in a manner that seeks their individual advice and does not involve collective judgment, or consensus advice or deliberation;

(d) solicit information from executive departments or agencies for purposes of carrying out its mission; and

(e) at the request of the head of any executive department or agency who is a member of the IGIA, with the approval of the Co-Chairs, promptly review and provide advice on a policy or policy implementation action affecting the Insular Areas proposed by that department or agency.

Sec. 3. *Recommendations.* The IGIA shall:

(a) submit annually to the President a report containing recommendations regarding the establishment or implementation of policies concerning the Insular Areas; and

(b) provide to the President, from time to time, as appropriate, recommendations concerning proposed or existing Federal programs and policies affecting the Insular Areas.

Sec. 4. *General Provisions.*

(a) The heads of executive departments and agencies shall assist and provide information to the IGIA, consistent with applicable law, as may be necessary to carry out the functions of the IGIA. Each executive department and agency shall bear its own expenses of participating in the IGIA.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof, or the status of that department or agency within the Federal Government; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order shall supersede Executive Order 13299 of May 8, 2003.

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

THE WHITE HOUSE,
April 14, 2010.

[FR Doc. 2010–9078
Filed 4–16–10; 8:45 am]
Billing code 3195–W0–P

Rules and Regulations

Federal Register
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Monday, April 19, 2010

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

7 CFR Part 3431

RIN 0524–AA43

Veterinary Medicine Loan Repayment Program (VMLRP)

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Final rule.

SUMMARY: This final rule establishes the process and procedures for designating veterinarian shortage situations, specifically for the Veterinary Medicine Loan Repayment Program (VMLRP) authorized by the National Veterinary Medical Service Act (NVMSA) and administered by the National Institute of Food and Agriculture (NIFA) of the U.S. Department of Agriculture. NIFA will designate geographic areas and other practice situations that have a shortage of food supply veterinarians in order to carry out the VMLRP goals of strengthening the nation's animal health infrastructure and supplementing the Federal response during animal health emergencies. NIFA will carry out NVMSA by entering into educational loan repayment agreements with veterinarians who agree to provide veterinary services in veterinarian shortage situations for a determined period of time. NIFA is establishing Subpart A for the designation of the veterinarian shortage situations and Subpart B for the administration of the VMLRP.

DATES: This final rule is effective April 19, 2010.

FOR FURTHER INFORMATION CONTACT: Gary Sherman; National Program Leader, Veterinary Science; National Institute of Food and Agriculture; U.S. Department of Agriculture; STOP 2220; 1400 Independence Avenue, SW.; Washington, DC 20250–2220; *Voice:* 202–401–4952; *Fax:* 202–401–6156; *E-mail: gsherman@nifa.usda.gov.*

SUPPLEMENTARY INFORMATION:

Establishment of National Institute of Food and Agriculture

On October 1, 2009, the Secretary of Agriculture (Secretary) established within USDA the National Institute of Food and Agriculture (NIFA), as mandated by section 251(f)(2) of the Department of Agriculture Reorganization Act of 1994 (Reorganization Act) (7 U.S.C. 6971(f)(2)). Section 251(f)(2) was added by section 7511 of the Food, Conservation, and Energy Act of 2008 (FCEA), Pub. L. 110–246. Pursuant to the FCEA, the Secretary transferred to NIFA, effective October 1, 2009, the authorities (including all budget authorities, available appropriations, and personnel), duties, obligations, and related legal and administrative functions prescribed by law or otherwise granted to the Secretary, the Department, or any other agency or official of the Department under the research, education, economic, cooperative State research programs, cooperative extension and education programs, international programs, and other functions and authorities delegated by the Under Secretary for Research, Education, and Economics ("REE") to the Administrator of the Cooperative State Research, Education, and Extension Service (CSREES) pursuant to 7 CFR 2.66, and any and all other authorities administered by the Administrator of CSREES. Accordingly, the agency known as CSREES was abolished upon establishment of NIFA.

Background and Purpose

In January 2003, the National Veterinary Medical Service Act (NVMSA) was passed into law adding section 1415A to the National Agricultural Research, Extension, and Teaching Policy Act of 1997 (NARETPA). This law established a new Veterinary Medicine Loan Repayment Program (7 U.S.C. 3151a) authorizing the Secretary of Agriculture to carry out a program of entering into agreements with veterinarians under which they agree to provide veterinary services in veterinarian shortage situations. In November 2005, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006 (Pub. L. 109–97) appropriated $495,000 to implement the Veterinary Medicine Loan Repayment Program (VMLRP) and represented the first time funds had been appropriated for this program. In February 2007, the Revised Continuing Appropriations Resolution, 2007 (Pub. L. 110–5) appropriated an additional $495,000 for support of the program, in December 2007, the Consolidated Appropriations Act, 2008 appropriated an additional $868,875 for support of this program, and on March 11, 2009, the Omnibus Appropriations Act, 2009 (Pub. L. 111–8) was enacted, providing an additional $2,950,000, for the VMLRP. In October 2009, the President signed into law, Public Law 111–80, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2010, which appropriated $4,800,000 for the VMLRP.

Consequently, there is a cumulative total of approximately $9.6 million available for NIFA to administer this program. Funding for future years will be based on annual appropriations and balances from prior years, and will likely vary from year to year.

Section 7105 of the Food, Conservation, and Energy Act of 2008, Public Law 110–246, (FCEA) amended section 1415A to revise the determination of veterinarian shortage situations to consider (1) geographical areas that the Secretary determines have a shortage of veterinarians; and (2) areas of veterinary practice that the Secretary determines have a shortage of veterinarians, such as food animal medicine, public health, epidemiology, and food safety. This section also added that priority should be given to agreements with veterinarians for the practice of food animal medicine in veterinarian shortage situations.

NARETPA section 1415A requires the Secretary, when determining the amount of repayment for a year of service by a veterinarian to consider the ability of USDA to maximize the number of agreements from the amounts appropriated and to provide an incentive to serve in veterinary service shortage areas with the greatest need. This section also provides that loan repayments may consist of payments of the principal and interest on government and commercial loans

received by the individual for the attendance of the individual at an accredited college of veterinary medicine resulting in a degree of Doctor of Veterinary Medicine or the equivalent. This program is not authorized to provide repayments for any government or commercial loans incurred during the pursuit of another degree, such as an associate or bachelor degree. Loans eligible for repayment include educational loans made for one or more of the following: Loans for tuition expenses; other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; and reasonable living expenses as determined by the Secretary. In addition, the Secretary is directed to make such additional payments to participants as the Secretary determines appropriate for the purpose of providing reimbursements to participants for individual tax liability resulting from participation in this program. Finally, this section requires USDA to promulgate regulations within 270 days of the enactment of FCEA (*i.e.,* June 18, 2008). The Secretary delegated the authority to carry out this program to NIFA.

Solicitation of Stakeholder Input and Publication of the Interim Rule

On August 29, 2008, CSREES published a **Federal Register** notice [73 FR 50928–50929] announcing a public meeting to be held on Monday, September 15, 2008, at the Waterfront Centre in Washington, DC, to solicit stakeholder input as well as the instructions on how to submit written comments by Tuesday, September 30, 2008, on the implementation of VMLRP.

CSREES received oral and written comments from the following veterinary professional associations and organizations: American Veterinary Medical Association (AVMA), Association of American Veterinary Medical Colleges (AAVMC), American College of Veterinary Microbiologists (ACVM), American Association of Veterinary Laboratory Diagnosticians (AAVLD), American College of Veterinary Pathologists (ACVP), National Cattlemen's Beef Association (NCBA), Texas Cattle Feeders Association (TCFA), and Ohio's Cattlemen Association (OCA) as well as a comprehensive joint statement from AVMA and the AAVMC. In addition, CSREES received 27 comments from individuals, most of whom were students at veterinary colleges. CSREES considered all comments received in the development of the interim rule which was published on July 9, 2009 [74 FR 32788–32798] with a 60-day comment period.

Response to Comments on Interim Rule and Revisions Included in Final Rule

In the Interim Rule, CSREES established rules and invited comments on the process and procedures for (a) designating veterinarian shortage situations and (b) administration for the VMLRP. CSREES received thirty-eight sets of comments from individuals, including practicing veterinarians, farmers, and students, and the following veterinary professional associations and organizations: American Veterinary Medical Association (AVMA), Association of American Veterinary Medical Colleges (AAVMC), American Association of Veterinary Laboratory Diagnosticians (AAVLD), National Association of Federal Veterinarians (NAFV), Humane Society Veterinary Medical Association (HSVMA), and North Dakota Stockmen's Association (NDSA) as well as a joint statement from Washington Cattlemen's Association (WCA) and Washington State Dairy Federation (WSDF). NIFA considered all comments received in the development of the final rule.

Non-Doctor of Veterinary Medicine (D.V.M.) Loans

Comment: Three commentors expressed concern about the exclusion of education loans other than those obtained for the Doctorate of Veterinary Medicine (or equivalent) from the VMLRP. AVMA, as one of the commentors, "contends that a veterinary student's undergraduate education is an integral component of their academic veterinary career. Veterinary students must take required prerequisites for the doctoral program while enrolled in undergraduate studies. Without these required prerequisite courses a prospective veterinary student would be ineligible for admission to veterinary medical school."

NIFA Response: The NVMSA legislation specifically states in Section 1415A(c)(3) of NARETPA the following: Qualifying Educational Loans—Loan repayments provided under this section may consist of payments on behalf of participating individuals of the principal, interest, and related expenses on government and commercial loans received by the individual for attendance of the individual at an accredited college of veterinary medicine resulting in a degree of Doctor of Veterinary Medicine or the equivalent * * *". Consequently, there is no change to the regulations regarding eligibility of non-DVM loans for the VMLRP.

Comment: Seven commentors observed that disqualifying individuals who consolidated their undergraduate student loans with veterinary school loans would unfairly cause a large group of highly qualified veterinarians, many of whom have high levels of debt, ineligible for the VMLRP. Additionally, AAVMC reported that "the issue of consolidated debt was the highest rated and most oft mentioned concern for AAVMC members."

NIFA Response: NIFA agrees. NIFA will allow individuals who consolidated their veterinary school loans with other educational loans (*e.g.* undergraduate) to apply for the VMLRP; however, only the eligible portion of the consolidation will be repaid by the VMLRP, thus Parts 3431.9(b)(3) and 3431.15(b)(4) have been removed from the final regulations. Furthermore, applicants with consolidated loans will be asked to provide a complete history of their student loans from the National Student Loan Database System (NSLDS), a central database for student aid operated by the U.S. Department of Education. The NSLDS Web site can be found at *http://www.nslds.ed.gov.* Individuals who consolidated their DVM loans with non-educational loans or loans belonging to an individual other than the applicant, such as a spouse or child, will continue to be ineligible for the VMLRP.

Definitions

Comment: Three commentors requested clarification on the definition for "accredited college of veterinary medicine" as there are multiple accreditation bodies that could be included in the definition. Two of the three commentors recommended that the definition be modified to specify accreditation by the AVMA Council on Education, a specialized accrediting agency recognized and authorized by the U.S. Department of Education.

NIFA Response: NIFA agrees. To eliminate any confusion, the definitions have been modified in the definitions (§ 3431.3) and eligibility (§ 3431.9) sections in the final regulations to specify that a veterinarian must have attended a college of veterinary medicine accredited by the AVMA Council on Education to be eligible to apply to the VMLRP.

Comment: One commentor asked NIFA to give serious consideration to including U.S. citizens who are studying to become veterinarians in veterinary schools in the Caribbean basin.

NIFA Response: NIFA welcomes veterinarians that studied abroad to obtain their Doctorate in Veterinary

Medicine degree (or equivalent) to apply for the VMLRP as long as the professional veterinary medicine degree was obtained from a college of veterinary medicine accredited by the AVMA Council on Education, a list that includes fourteen schools outside the United States as of October 21, 2009.

Comment: Two commentors, AVMA and NAFV, recommended adding "animal health" to the definition of "practice of food supply veterinary medicine" and the areas that have food supply veterinarian shortages.

NIFA Response: NIFA agrees. "Animal health" has been added to both definitions in the definitions section (§ 3431.3) in the final regulations.

Comment: One commentor recommended that "caprine" be added to the definition of "Food animal".

NIFA Response: "Caprine" has been added to the definition of "food animal" in the definitions section (§ 3431.3).

State Animal Health Official

Comment: Three commentors suggested that the State Animal Health Official be required to consult with the State Veterinary Association and other interested parties within the State when identifying underserved areas within a State.

NIFA Response: We strongly recommend that State Animal Health Officials involve other leading animal health experts in the nomination process as they identify underserved areas within their respective States.

Shortage Nominations

Comment: One commentor expressed concern that low density agricultural areas will be regarded as less important than areas of heavily concentrated agriculture.

Comment: One commentor recommended that representatives of Federal agencies be included on an official review panel.

NIFA Response: NIFA will take these comments into consideration as it develops the solicitation for nominations for veterinarian shortage situations and implements the review panel.

Comment: One commentor urged USDA to examine the feasibility of establishing an indexing system whereby each shortage situation that is designated is awarded a weighted score for severity of shortage.

NIFA Response: As with other review processes conducted by NIFA, the review panel will evaluate the composite qualitative and quantitative arguments presented in the submitted nomination packages against criteria described elsewhere in this notice. The panel will classify each shortage situation as either "Recommended for designation" or "Not recommended for designation".

Comment: One commentor suggested that solicitation notices be published on an annual basis instead of a biennial basis. Another commentor requested clarification on the frequency of the need to apply for the designation of shortage areas and the need to reassess a designation once it is filled by a veterinarian enrolled in the VMLRP.

NIFA Response: NIFA presumes that, over time, the shortage situation priorities of a State will change due to veterinarians relocating to fill critical areas designated by the VMLRP. NIFA will also be mindful of spontaneous shifts in perceived threats to animal health in time and space. To address changing conditions, NIFA program staff will assess the relative demand for reprioritization of shortage situation distribution within the States on an annual basis. However, NIFA reserves the right to conduct this solicitation on a biennial basis to save administrative costs and to adhere to the aggressive annual program schedule and/or to respond to funding fluctuations.

Selection Process

Comment: One commentor stated that the Interim Rule did not address how applicants would be chosen for specific shortage areas.

NIFA Response: NIFA will establish the evaluation criteria and process and determine the makeup of the application review panel before the application period opens. Applicants will be ranked based on their qualifications relative to the attributes of the shortage situation applied for.

Licensure

Comment: One commentor recommended that licensure not be a blanket requirement for eligibility to apply for the VMLRP, but that veterinarians should be in compliance with State and local regulations, including having the appropriate certifications and licenses, in the jurisdiction of the shortage situation.

NIFA Response: NIFA agrees and has updated Parts 3431.8 and 3431.10 of the regulations to reflect that licensure is required only if it is mandated by the State and local regulations in which the shortage situation is sited.

Federal Veterinarians

Comment: Three commentors stated that it was not clear to what degree the VMLRP would apply to veterinarians working for the Federal government.

NIFA Response: NIFA recognizes that NVMSA is intended to address a national problem. NIFA has also acknowledged in the interim rule that approximately 10 percent of the loan repayment awards will be made available to address public practice shortages and at least 90 percent of funds will be awarded to private practice food animal veterinarians to assure appropriate emphasis as requested by the legislation set forth by Congress. Hence, some designated veterinarian shortage situations may be Federal positions. However, these positions must be nominated by the State Animal Health Official (SAHO), designated by the review panel as "recommended for designation," and approved by the Secretary for designation.

Retention

Comment: Fourteen commentors stated the importance of making VMLRP awards to include veterinarians with established practices in shortage areas as a form of retention in addition to the recruitment of veterinarians to shortage areas.

NIFA Response: NIFA agrees. The SAHO may identify and submit a shortage situation based on the assessment that there is a great risk of losing an established veterinarian in a given shortage situation and that the need to retain a veterinarian in this area is of utmost importance.

Appropriation

Comment: Three commentors mentioned the importance of having adequate, stable, and reliable funding. AVMA and NAFV also stated that NIFA should move towards optimal funding of $6 million each year through fiscal year 2016.

NIFA Response: NIFA and USDA both support the President's proposed budget each year. Congress is ultimately responsible for the development and passage of the annual Federal appropriations bill. As NIFA is prohibited from lobbying Congress, the stability and magnitude of future Federal funding for the VMLRP will depend on Congressional consideration of Presidential recommendations and public interests balanced against other fiscal priorities.

Allocation of Awards

Comment: One commentor suggested that 90 percent of awards be devoted to veterinarians involved with food animal medicine and rural practice (mixed large animal and small animal) who have at least 30 percent or more involvement with food animal species.

Another commentor recommended that the 10 percent of the awards offered to mixed animal practitioners be devoted to the food animal discipline for at least half of their practice.

NIFA Response: NIFA agrees with the notion that there is practical value in identifying service commitment requirements for practitioners of food supply veterinary medicine of less than 100 percent. Accordingly, all three shortage situation types identified in the nomination form allow for different percentages of full-time equivalent commitment, commensurate with a variety of different public and private practice scenarios.

Scholarships

Comment: One commentor recommended that USDA allocate four scholarships to the Washington State University College of Veterinary Medicine to allow students to pay down principal and interest on qualifying loans accrued while a veterinary student.

NIFA Response: NIFA appreciates and accepts all comments. However, this comment is beyond the scope of the VMLRP as the VMLRP is a competitive program and its benefits apply to educational loans taken out by graduates of a school of veterinary medicine. Furthermore, participants are required to hold a Doctor of Veterinary Medicine degree or the equivalent and serve in a shortage area immediately in order to receive VMLRP benefits.

Mentoring

Comment: Two commentors urged NIFA to establish a mentoring program for participants in the program.

NIFA Response: NIFA agrees. NIFA will investigate options for including a mentoring component as part of the VMLRP.

Debt Threshold

Comment: Two commentors questioned the need to have a debt threshold for individuals to be eligible to apply to the VMLRP.

NIFA Response: NIFA disagrees. If there are veterinarians with minimal amounts of educational debt that are willing to commit for a number of years of service to a shortage situation, they should be able to do so without the VMLRP benefit. The goal of the VMLRP is to fill shortage situations with veterinarians that would have otherwise gone elsewhere. NIFA also aims to maximize the number of agreements, and entering agreements with those with negligible debt would create an additional administrative burden (both cost and personnel time) as an individual's debt level has no effect on the administrative cost to process an application and execute a service agreement. Establishing a debt threshold eliminates the administrative burden of processing applications from those who will scarcely benefit from the VMLRP.

Diagnostic Lab

Comment: Two commentors requested NIFA to recognize the shortage of veterinarians in AAVLD laboratories and to allow veterinarians entering the diagnostic laboratory workforce to be considered under the category of "public practice".

NIFA Response: Veterinarians entering the diagnostic laboratory workforce will be eligible for the VMLRP under the public practice nomination provisions and limitations. The number of agreements available to this area depends on (a) the nominations by the SAHOs, and (b) recommendations of designation by the review panel.

Emergency Situations

Comment: Two commentors stated their support for the concept of the proposed pilot program for VMLRP participants to be called away to work in emergency situations. However, both commentors also shared concerns about the proper implementation of this component of the program.

NIFA Response: Due to limited funding and the intricacies involving the emergency component, this component will not be implemented during the first year of the VMLRP.

Long-Term Program Impact

Comment: Two commentors expressed concern about the focus of the VMLRP. One commentor stated that "It seems that many of these types of programs end up helping those who have a background and obvious desire to already go into such a career." The other commentor cited a program where "most of the nurses, and other health care workers, only remain there as long as is necessary to receive the payback and leave as quickly as possible thereafter leaving the reservation's health care no better off than it was before."

NIFA response: NIFA appreciates all comments both positive and negative. NIFA plans to conduct an impact evaluation on the VMLRP to assess whether the desired outcomes are achieved.

Program Benefits

Comment: One commentor recommended that the amount of funding provided to cover a VMLRP recipient's tax obligation be reviewed every three years to assure tax coverage is adequate.

NIFA Response: NIFA will reassess the tax percentage every three years to ensure VMLRP participants are provided proper tax coverage. Section 3431.13(e) has been broadened to allow that the amount provided for reimbursement of tax liabilities will not exceed "any other cap established by the Secretary."

Increasing Educational Debt

Comment: Five commentors stated concerns about rising educational debt for aspiring veterinarians. One commentor questioned whether the maximum annual loan repayment of $25,000 was sufficient. Another commentor stated that adjustments need to be included to allow for increases in annual loan limits. Yet another commentor stated that the $25,000 repayment level is a meaningful amount that will help address the educational debt load.

NIFA Response: After program implementation, NIFA will continue to monitor trends among participants, applicants, and graduating veterinarians to ensure the VMLRP remains successful in providing a financial incentive to fill shortage areas, while maximizing the number of agreements at the same time.

Other Revisions to the Interim Regulation

A correction was made to the Withdrawal definition in § 3413.3 to signify that a withdrawal occurs prior to the VMLRP making the first *quarterly* payment on behalf of the participant rather than the first annual payment.

Timeline for Implementing the Program

NIFA published a solicitation for the veterinarian shortage situations via a **Federal Register** notice on January 22, 2010 [75 FR 3697–3704] with a solicitation period of 45 days. At the same time, NIFA will continue to work with the NIH DLR on adapting the NIH DLR application forms for use by VMLRP as well as developing the other associated business processes (*e.g.,* reporting, payments). NIFA anticipates soliciting for VMLRP participants in April 2010 (open for 60 days).

In addition to this final regulation, which addresses most of the policies associated with this program, NIFA plans to create informational Web pages (providing detailed information and procedures) for the program similar to the pages created for the NIH DLR programs.

Please note that the solicitation for veterinary shortage situations and the VMLRP RFA will provide more specific details on the program.

Administrative Requirements for the Final Rulemaking

Executive Order 12866

The Office of Management and Budget has reviewed this final rule because while it is not economically significant, it implements the Veterinary Medicine Loan Repayment Program (VMLRP). This final rule will not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs; nor will it have an annual effect on the economy of $100 million or more; nor will it adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way. Furthermore, it does not raise a novel legal or policy issue arising out of legal mandates, the President's priorities or principles set forth in the Executive Order.

Regulatory Flexibility Act of 1980

This final rule has been reviewed in accordance with the Regulatory Flexibility Act of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601–612. The Department concluded that the rule does not involve regulatory and informational requirements regarding businesses, organizations, and governmental jurisdictions subject to regulation.

Paperwork Reduction Act

The Department certifies that this final rule has been assessed in accordance with the requirements of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (PRA). The VMLRP Veterinarian Shortage Situation Nomination form has been approved by OMB as No. 0524–0046. The VMLRP Application Package and Reporting Requirements have been approved by OMB as No. 0524–0047.

Catalog of Federal Domestic Assistance

This interim regulation applies to the following Federal assistance program administered by NIFA, Catalog of Federal Domestic Assistance (CFDA) No. 10.313, Veterinary Medicine Loan Repayment Program (VMLRP).

Unfunded Mandates Reform Act of 1995 and Executive Order 13132

The Department has reviewed this final rule in accordance with the requirements of Executive Order No. 13132, 64 FR 43225 (August 10, 1999) and the Unfunded Mandates Act of 1995, 2 U.S.C. 1501 *et seq.,* and has found no potential or substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. As there is no Federal mandate contained herein that could result in increased expenditures by State, local Tribal governments or by the private sector, the Department has not prepared a budgetary impact statement.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

The Department has reviewed this final rule in accordance with Executive Order 13175, 65 FR 67249 (Nov. 9, 2000), and has determined that it does not have "tribal implications." The final rule 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."

Clarity of This Regulation

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. The Department invites comments on how to make this final rule easier to understand.

List of Subjects in Part 3431

Administrative practice and procedure, Agricultural research, education, extension, Federal assistance, Veterinarians.

■ For the reasons discussed in the preamble, NIFA amends Chapter XXXIV of Title 7 of the Code of Federal Regulations as follows:

Chapter XXXIV—National Institute of Food and Agriculture

■ 1. The heading of chapter XXXIV is revised to read as set forth above.

■ 2. Part 3431 is revised to read as follows:

PART 3431—VETERINARY MEDICINE LOAN REPAYMENT PROGRAM

Subpart A—Designation of Veterinarian Shortage Situations

Subpart B—Administration of the Veterinary Medicine Loan Repayment Program

Authority: 7 U.S.C. 3151a; Pub. L. 106–107 (31 U.S.C. 6101 note).

Subpart A—Designation of Veterinarian Shortage Situations

§ 3431.1 Applicability of regulations.

This part establishes the process and procedures for designating veterinarian shortage situations as well as the administrative provisions for the Veterinary Medicine Loan Repayment Program (VMLRP) authorized by the National Veterinary Medical Service Act (NVMSA), 7 U.S.C. 3151a.

§ 3431.2 Purpose.

The Secretary will follow the processes and procedures established in subpart A of this part to designate veterinarian shortage situations for the VMLRP. Applications for the VMLRP will be accepted from eligible veterinarians who agree to serve in one of the designated shortage situations in exchange for the repayment of an amount of the principal and interest of the veterinarian's qualifying educational loans. The administrative provisions for the VMLRP, including the application process, are established in subpart B of this part.

§ 3431.3 Definitions and acronyms.

(a) *General definitions.* As used in this part:

Act means the National Veterinary Medical Service Act, as amended.

Agency or NIFA means the National Institute of Food and Agriculture.

Department means the United States Department of Agriculture.

Food animal means the following species: Bovine, porcine, ovine/camelid, cervid, poultry, caprine, and any other species as determined by the Secretary.

Food supply veterinary medicine means all aspects of veterinary medicine's involvement in food supply

systems, from traditional agricultural production to consumption.

Insular area means the Commonwealth of Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and the Virgin Islands of the United States.

NVMSA means the National Veterinary Medicine Service Act.

Practice of food supply veterinary medicine includes corporate/private practices devoted to food animal medicine, mixed animal medicine located in a rural area (at least 30 percent of practice devoted to food animal medicine), food safety, epidemiology, public health, animal health, and other public and private practices that contribute to the production of a safe and wholesome food supply.

Practice of veterinary medicine means to diagnose, treat, correct, change, alleviate, or prevent animal disease, illness, pain, deformity, defect, injury, or other physical, dental, or mental conditions by any method or mode; including:

(1) The prescription, dispensing, administration, or application of any drug, medicine, biologic, apparatus, anesthetic, or other therapeutic or diagnostic substance or medical or surgical technique, or

(2) The use of complementary, alternative, and integrative therapies, or

(3) The use of any manual or mechanical procedure for reproductive management, or

(4) The rendering of advice or recommendation by any means including telephonic and other electronic communications with regard to any of paragraphs (1), (2), (3), or (4) of this definition.

Rural area means any area other than a city or town that has a population of 50,000 inhabitants and the urbanized area contiguous and adjacent to such a city or town.

Secretary means the Secretary of Agriculture and any other officer or employee of the Department to whom the authority involved has been delegated.

Service area means geographic area in which the veterinarian will be providing veterinary medical services.

State means any one of the fifty States, the District of Columbia, and the insular areas of the United States.

State animal health official or SAHO means the State veterinarian, or equivalent, who will be responsible for nominating and certifying veterinarian shortage situations within the State.

Veterinarian means a person who has received a professional veterinary medicine degree from a college of veterinary medicine accredited by the AVMA Council on Education.

Veterinarian shortage situation means any of the following situations in which the Secretary, in accordance with the process in subpart A of this part, determines has a shortage of veterinarians:

(1) Geographical areas that the Secretary determines have a shortage of food supply veterinarians; and

(2) Areas of veterinary practice that the Secretary determines have a shortage of food supply veterinarians, such as food animal medicine, public health, animal health, epidemiology, and food safety.

Veterinary medicine means all branches and specialties included within the practice of veterinary medicine.

Veterinary Medicine Loan Repayment Program or VMLRP means the Veterinary Medicine Loan Repayment Program authorized by the National Veterinary Medical Service Act.

(b) *Definitions applicable to Subpart B.*

Applicant means an individual who applies to and meets the eligibility criteria for the VMLRP.

Breach of agreement results when a participant fails to complete the service agreement obligation required under the terms and conditions of the agreement and will be subject to assessment of monetary damages and penalties as determined in the service agreement, unless a waiver has been granted or an exception applies.

Current payment status means that a qualified educational loan is not past due in its payment schedule as determined by the lending institution.

Debt threshold means the minimum amount of qualified student debt an individual must have, on their program eligibility date, in order to be eligible for program benefits, as determined by the Secretary.

Program eligibility date means the date on which an individual's VMLRP agreement is executed by the Secretary.

Program participant means an individual whose application to the VMLRP has been approved and whose service agreement has been accepted and signed by the Secretary.

Qualifying educational expenses means the costs of attendance of the applicant at a college of veterinary medicine accredited by the AVMA Council on Education, exclusive of the tuition and reasonable living expenses. Educational expenses may include fees, books, laboratory expenses and materials, as required by an accredited college or school of veterinary medicine as part of a Doctor of Veterinary Medicine degree program, or the equivalent. The program participant must submit sufficient documentation, as required by the Secretary, to substantiate the school requirement for the educational expenses incurred by the program participant.

Qualifying educational loans means loans that are issued by any Federal, State, or local government entity, accredited academic institution(s), and/or commercial lender(s) that are subject to examination and supervision in their capacity as lending institutions by an agency of the United States or the State in which the lender has its principal place of business. Loans must have been made for one or more of the following: School tuition, other qualifying educational expenses, or reasonable living expenses relating to the obtainment of a degree of Doctor of Veterinary Medicine from a college or school of veterinary medicine accredited by the AVMA Council on Education. Such loans must have documentation which is contemporaneous with the training received in a college or school of veterinary medicine. If qualifying educational loans are refinanced, the original documentation of the loan(s) will be required to be submitted to the Secretary to establish the contemporaneous nature of such loans.

Reasonable living expenses means the ordinary living costs incurred by the program participant while attending the college of veterinary medicine, exclusive of tuition and educational expenses. Reasonable living expenses must be incurred during the period of attendance and may include food and lodging expenses, insurance, commuting and transportation costs. Reasonable living expenses must be equal to or less than the sum of the school's estimated standard student budgets for living expenses for the degree of veterinary medicine for the year(s) during which the program participant was enrolled in the school. However, if the school attended by the program participant did not have a standard student budget or if a program participant requests repayment for living expenses which are in excess of the standard student budgets described in the preceding sentence, the program participant must submit documentation, as required by the Secretary, to substantiate the reasonableness of living expenses incurred. To the extent that the Secretary determines, upon review of the program participant's documentation, that all or a portion of

the living expenses are reasonable, these expenses will qualify for repayment.

Service agreement means the agreement, which is signed by an applicant and the Secretary for the VMLRP wherein the applicant agrees to accept repayment of qualifying educational loans and to serve in accordance with the provisions of NVMSA for a prescribed period of obligated service.

Termination means a waiver of the service obligation granted by the Secretary when compliance by the participant is impossible, would involve extreme hardship, or where enforcement with respect to the individual would be unconscionable (*see* breach of agreement).

Withdrawal means a request by a participant for withdrawal from participation in the VMLRP after signing the service agreement, but prior to VMLRP making the first quarterly payment on behalf of the participant. A withdrawal is without penalty to the participant and without obligation to the Program.

§ 3431.4 Solicitation of stakeholder input.

The Secretary will solicit stakeholder input on the process and procedures used to designate veterinarian shortage situations prior to the publication of the solicitation for nomination of veterinarian shortage situations. A notice may be published in the **Federal Register**, on the Agency's Web site, or other appropriate format or forum. This request for stakeholder input may include the solicitation of input on the administration of VMLRP and its impact on meeting critical veterinarian shortage situations. All comments will be made available and accessible to the public.

§ 3431.5 Solicitation of veterinarian shortage situations.

(a) *General.* The Secretary will follow the procedures described in this part to solicit veterinarian shortage situations as the term is defined in § 3431.3.

(b) *Solicitation.* The Secretary will publish a solicitation for nomination of veterinarian shortage situations in the **Federal Register**, on the Agency's Web site, or other appropriate format or forum.

(c) *Frequency.* Contingent on the availability of funds, the Secretary will normally publish a solicitation on an annual basis. However, the Secretary reserves the right to solicit veterinarian shortage situations every two or three years, as appropriate.

(d) *Content.* The solicitation will describe the nomination process, the review criteria and process, and include the form used to submit a nomination. The solicitation may specify the maximum number of nominations that may be submitted by each State animal health official.

(e) *Nominations.* Nominations shall identify the veterinarian shortage situation and address the criteria in the nomination form which may include the objectives of the position, the activities of the position, and the risk posed if the position is not secured.

(f) *Nominating Official.* The State animal health official in each State is the person responsible for submitting and certifying veterinarian shortage situations within the State to NIFA officials. It is strongly recommended that the State animal health official of each State involve the leading health animal experts in the State in the nomination process.

§ 3431.6 Review of nominations.

(a) *Peer panel.* State shortage situations nominations will be evaluated by a peer panel of experts in animal health convened by the Secretary. The panel will evaluate nominations according to the criteria identified in the solicitation. The panel will consider the objectives and activities of the veterinarian position in the veterinary service shortage situation and the risks associated with not securing or retaining the position and make a recommendation regarding each nomination.

(b) *Agency review.* The Secretary will evaluate the recommendations of the peer panel and designate shortage situations for the VMLRP.

§ 3431.7 Notification and use of designated veterinarian shortage situations.

The Secretary will publish the designated veterinarian shortage situations on the Agency's Web site and will use the designated veterinarian shortage situations to solicit VMLRP loan repayment applications from individual veterinarians in accordance with subpart B of this part.

Subpart B—Administration of the Veterinary Medicine Loan Repayment Program

§ 3431.8 Purpose and scope.

(a) *Purpose.* The regulations of this subpart apply to the award of veterinary medicine loan repayments under the Veterinary Medicine Loan Repayment Program (VMLRP) authorized by the National Veterinary Medicine Service Act, 7 U.S.C. 3151a.

(b) *Scope.* Under the VMLRP, the Secretary enters into service agreements with veterinarians to pay principal and interest on education loans of veterinarians who agree to work in veterinary shortage situations for a prescribed period of time. In addition, program participants may enter into an agreement to provide services to the Federal government in emergency situations in exchange for salary, travel, per diem expenses, and additional amounts of loan repayment assistance. The purpose of the program is to assure an adequate supply of trained food animal veterinarians in shortage situations and provide USDA with a pool of veterinary specialists to assist in the control and eradication of animal disease outbreaks.

§ 3431.9 Eligibility to apply.

(a) *General.* To be eligible to apply to the VMLRP an applicant must:

(1) Have a degree of Doctor of Veterinary Medicine (DVM), or the equivalent, from a college of veterinary medicine accredited by the AVMA Council on Education;

(2) Have qualifying educational loan debt as defined in § 3431.3;

(3) Secure an offer of employment or establish and/or maintain a practice in a veterinary shortage situation, as determined by the Secretary in accordance with the procedures in subpart A of this part, within the time period specified in the VMLRP service agreement offer; and

(4) Provide certifications and verifications in accordance with § 3431.16.

(b) *Non-eligibility.* The following individuals are ineligible to apply to the VMLRP:

(1) An individual who owes an obligation for veterinary service to the Federal government, a State, or other entity under an agreement with such Federal, State, or other entity are ineligible for the VMLRP unless such obligation will be completely satisfied prior to the beginning of service under the VMLRP;

(2) An individual who has a Federal judgment lien against his/her property arising from Federal debt; and

(3) An individual who has total qualified debt that does not meet the debt threshold.

§ 3431.10 Eligibility to participate.

To be eligible to participate in the VMLRP, a participant must meet the following criteria:

(a) Meet the eligibility criteria of § 3431.9 for applying to the VMLRP;

(b) Be selected for participation by the Secretary pursuant to § 3431.12.

(c) Comply with all State and local regulations (including appropriate licensure where required) in the jurisdiction in which he or she proposes to practice;

(d) Be a citizen, national, or permanent resident of the United States;

(e) Sign a service agreement to provide veterinary services in one of the veterinarian shortage situations; and

(f) Comply with the terms and conditions of the Service Agreement.

§ 3431.11 Application.

Individuals who meet the eligibility criteria of § 3431.9 may submit an online program application or any other application process provided by the Secretary.

§ 3431.12 Selection of applicants.

(a) *Review of applications.* Upon receipt, applications for the VMLRP will be reviewed for eligibility and completeness by the appropriate staff as determined by the Secretary. Incomplete or ineligible applications will not be processed or reviewed.

(b) *Peer review.* (1) Applications for the VMLRP that are deemed eligible and complete will be referred to the VMLRP peer panel for peer review. In evaluating the application, reviewers are directed to consider the following components, as well as any other criteria identified in the RFA, and how they relate to the likelihood that the applicant will meet the terms and conditions of the VMLRP agreement, continue to serve in a veterinary shortage situation, or pursue a career in food supply veterinary medicine:

(i) Major or emphasis area(s) during formal post-secondary training (*e.g.,* bachelors degree major, minor);

(ii) Major or emphasis area(s) during formal training for DVM/VMD degree;

(iii) Specialty training area/discipline (*e.g.,* board certification or graduate degree);

(iv) Non-degree/non-board certification training or certifications (*e.g.,* animal agrosecurity coursework and certifications);

(v) Applicant's personal statement;

(vi) Awards;

(vii) Letters or recommendation, if applicable; and

(viii) Other documentation or criteria, as specified in the RFA.

(2) Applicants will then be ranked based on their qualifications relative to the attributes of the shortage situation applied for.

§ 3431.13 Terms of loan repayment and length of service requirements.

(a) *Loan repayment.* For each year of obligated service in a veterinary shortage situation, as determined by the Secretary, with a minimum of 3 years (and maximum of 4 years) of obligated service, the Secretary may pay:

(1) An amount not exceeding $25,000 per year of a program participant's qualifying loans; and

(2) An additional amount not exceeding $5,000 per year of a program participant's qualifying loans, if the program participant has already been selected for participation in the VMLRP and agrees to enter into a one-year agreement for each year of service to provide up to 60 days of obligated service to the Federal government in animal health emergency situations, as determined by the Secretary, provided the shortage situation in which the participant has agreed to serve has been designated as suitable for the Federal obligated service.

(b) To maximize the number of agreements and to encourage qualified veterinarians to participate in the VMLRP, the Secretary may establish a loan repayment cap that differs from the cap established under paragraph (a)(1) and (a)(2) of this section when it is in the best interest of VMLRP. This will be identified in the RFA.

(c) The Secretary will determine the debt threshold in the RFA.

(d) Loan repayments will be made directly to the loan provider on a quarterly basis, starting with the end of the first quarter after the program eligibility date of the service agreement. Tax payments equal to 39 percent of the loan repayments will be credited directly to the participant's IRS (Federal tax) account simultaneously with each loan repayment.

(e) Once a service agreement has been signed by both parties, the Secretary will obligate such funds as will be necessary to ensure that sufficient funds will be available to make loan repayments and tax payments, as specified in the service agreement, for the duration of the period of obligated service. Reimbursements for tax liabilities in excess of the amount provided (not to exceed 39 percent of the amount of loan repayment or any other cap established by the Secretary) will be subject to the availability of funds. These additional tax payments, if available to the VMLRP participants, will be identified in the RFA and in the participant service agreement.

(f) Participants are required to keep payments current on all qualifying VMLRP loans.

(g) *Travel expenditures.* The VMLRP will not reimburse a program participant for expenses associated with traveling from the program participant's residence to the prospective practice site for the purpose of evaluating such site or the expenses of relocating from the program participant's temporary or permanent residence to a practice site.

§ 3431.14 Priority.

Pursuant to NVMSA, the Secretary will give priority to agreements with veterinarians for the practice of food animal medicine in veterinarian shortage situations, as determined by the Secretary. The Secretary may establish additional criteria in the RFA for assigning priority levels to veterinarian shortage situations nominated for award.

§ 3431.15 Qualifying loans.

(a) *General.* Loan repayments provided under the VMLRP may consist of payments on behalf of participating individuals of the principal and interest on qualifying educational loans received by the individual for attendance of the individual at an accredited college of veterinary medicine resulting in a degree of Doctor of Veterinary Medicine, or the equivalent, which loans were made for one or more of the following:

(1) Tuition expenses;

(2) All other reasonable educational expenses, as defined in this part and as determined by the Secretary; and

(3) Reasonable living expenses, as defined in this part and as determined by the Secretary.

(b) *Non-eligible loans.* The following loans are ineligible for repayment under the VMLRP:

(1) Loans not obtained from a bank, credit union, savings and loan association, not-for-profit organization, insurance company, school, and other financial or credit institution which is subject to examination and supervision in its capacity as lending institution by an agency of the United States or of the State in which the lender has its principal place of business;

(2) Loans for which supporting documentation is not available;

(3) Loans that have been consolidated with loans of other individuals, such as spouses or children;

(4) Loans or portions of loans obtained for educational or living expenses which exceed the standard of reasonableness as determined by the participant's standard school budget for the year in which the loan was made, and are not determined by the Secretary, to be reasonable based on additional documentation provided by the individual;

(5) Loans, financial debts, or service obligations incurred under another loan repayment or scholarship program, or similar programs, which provide loans, scholarships, loan repayments, or other awards in exchange for a future service obligation;

(6) Non-educational loans, including home equity loans; and

(7) Any loan in default, delinquent, or not in a current payment status.

§ 3431.16 Certifications and verifications.

(a) The application for the loan repayment program shall include a personal statement describing how the applicant would meet the requirements of:

(1) The veterinary service shortage situations as defined in the RFA;

(2) The eligibility criteria for application of section § 3431.9 of this part; and

(3) The selection priority of § 3431.14 of this part.

(b) The applicant shall provide sufficient documentation to establish that the applicant has qualifying loans as described in § 3431.15 of this part.

(c) The applicant shall provide sufficient documentation to establish that the applicant has the capacity to secure an offer of employment or establish and/or maintain a veterinary practice in a veterinary service shortage situation as defined in subpart A of this part.

(d) The applicant shall provide, if applicable, sufficient documentation to establish that the applicant is licensed to practice veterinary medicine in the jurisdiction in which the applicant has an offer of employment.

(e) The applicant shall provide, if applicable, the required documentation to establish whether the applicant receives payments under any other Federal, State, institutional, or private loan repayment programs.

(f) The applicant shall provide the required documentation to show that he/she has completed, or is in the process of completing, the National Veterinary Accreditation Program (NVAP) if national accreditation is required for the veterinary shortage position for which the applicant has an offer of employment.

(g) The applicant shall provide authorization to the appropriate staff as designated by the Secretary to obtain a copy of the participant's credit report.

§ 3431.17 VMLRP service agreement offer.

The Secretary will make an offer to successful applicants to enter into an agreement with the Secretary to provide veterinary services under the VMLRP. As part of the offer, successful VMLRP applicants will be provided a specific period of time, as defined in the RFA, to secure an offer of employment or establish and/or maintain a veterinary practice in a veterinary shortage situation.

§ 3431.18 Service agreement.

(a) The service agreement shall be signed by the program participant and the Secretary after acceptance of the terms and conditions of the loan repayment program by the program participant.

(b) The service agreement shall specify the period of obligated service.

(c) The service agreement shall specify the amount of loan repayment to be paid for each year of obligated service.

(d) The service agreement shall contain a provision defining when a breach of the agreement by the program participant has occurred.

(e) The service agreement shall provide remedies for the breach of a service agreement by a program participant, including repayment or partial repayment of financial assistance received, with interest.

(f) The service agreement shall include provisions addressing the granting of a waiver by the Secretary in case of hardship.

(g) Payments under the service agreement do not exempt a program participant from the responsibility and/or liability for any loan(s) for which he or she is obligated, as the Secretary is not obligated to the lender/note holder for its commitment to the program participant.

(h) During the term of the service agreement, the program participant shall agree that the Secretary or the designated VMLRP service provider is authorized to verify the status of each loan for which the Secretary will be reimbursing the participant.

(i) The service agreement shall contain certifications, as determined by the Secretary.

(j) The service agreement shall contain provisions addressing the income tax liability of the program participant and the availability of reimbursement of taxes incurred as a result of an individual's participation in the VMLRP.

(k) *Renewal.* The service agreement will indicate whether the existing service agreement may be renewed. However, renewal applications are subject to peer review and approval, acceptance is not guaranteed, and the position must still be considered a veterinarian shortage situation at the time of application for renewal. The Secretary may request additional documentation in connection with the review and approval of a renewal application. The Secretary reserves the right not to offer renewals. Any requests for renewal applications will be solicited via the RFA.

(l) The service agreement shall contain participant reporting requirements (*e.g.,* quarterly, annual, and/or close-out) to allow for program monitoring and evaluation.

§ 3431.19 Payment and tax liability.

(a) *Loan repayment.* Loan repayments pursuant to a service agreement are made directly to a participant's lender(s) by the Secretary or the VMLRP service provider. If there is more than one outstanding qualified educational loan, the Secretary will repay the loans in the following order, unless the Secretary determines significant savings to the program would result from paying loans in a different order of priority:

(1) Loans guaranteed by the U.S. Department of Education;

(2) Loans made or guaranteed by a State;

(3) Loans made by a School; and

(4) Loans made by other entities, including commercial loans.

(b) *Tax Liability Payments.* Tax payments equal to 39 percent of the total loan repayment amount will be credited directly to the participant's IRS (Federal tax) account simultaneously with each loan payment. The Secretary may make payments of an amount not to exceed 39 percent of the actual annual loan repayments made in a calendar year for all or part of the increased Federal, State, and local tax liability resulting from loan repayments received under the VMLRP. However, the Secretary may increase the cap, if appropriate. Supplementary payments for increased tax liability may be made for the actual amount of tax liability associated with the receipt of loan repayments under the VMLRP. Availability of these additional tax liability payments (*i.e.,* in excess of 39 percent or other approved cap) will be identified in the RFA and in the participant service agreement. Program participants wishing to receive tax liability payments will be required to submit their requests for such payments in a manner prescribed by the Secretary and must provide the Secretary with any documentation the Secretary determines is necessary to establish a program participant's increased tax liability. Tax liability payments in excess of 39 percent or other approved cap will be made on a reimbursement basis only.

(c) Under § 3431.19(a) and (b), the Secretary will make loan and tax liability payments to the extent appropriated funds are available for these purposes.

§ 3431.20 Administration.

The VMLRP will be administered by NIFA, Office of Extramural Programs (OEP). OEP may carry out this program directly or enter into agreements with

another Federal agency or other service provider to assist in the administration of the VMLRP. However, the determination of the veterinarian shortage areas, peer review of individual VMLRP applications, and the overall VMLRP oversight and coordination will reside with the Secretary.

§ 3431.21 Breach.

(a) *General.* If a program participant fails to complete the period of obligated service incurred under the service agreement, including failing to comply with the applicable terms and conditions of a waiver granted by the Secretary, the program participant must pay to the United States an amount as determined in the service agreement. Payment of this amount shall be made within 90 days of the date that the program participant failed to complete the period of obligated service, as determined by the Secretary.

(b) *Exceptions.*

(1) A termination of service for reasons that are beyond the control of the program participant will not be considered a breach.

(2) A transfer of service from one shortage situation to another, if approved by the Secretary, will not be considered a breach.

(3) A call or order to active duty will not be considered a breach.

(c) The Secretary may renegotiate the terms of a participant's service agreement in the event of a transfer, termination or call to active duty pursuant to paragraph (b) of this section.

(d) *Amount of repayment.* The service agreement shall provide the method for the calculation of the amount owed by a program participant who has breached a service agreement.

(e) *Debt Collection.* Individuals in breach of a service agreement entered into under this part are considered to owe a debt to the United States for the amount of repayment. Any such debt will be collected pursuant to the Department's Debt Management regulations at 7 CFR part 3.

§ 3431.22 Waiver.

(a) A program participant may seek a waiver or suspension of the service or payment obligations incurred under this part by written request to the Secretary setting forth the bases, circumstances, and causes which support the requested action.

(b) The Secretary may waive any service or payment obligation incurred by a program participant whenever compliance by the program participant is impossible or would involve extreme hardship to the program participant and if enforcement of the service or payment obligation would be against equity and good conscience.

(1) Compliance by a program participant with a service or repayment obligation will be considered impossible if the Secretary determines, on the basis of information and documentation as may be required:

(i) That the program participant suffers from a physical or mental disability resulting in the permanent inability of the program participant to perform the service or other activities which would be necessary to comply with the obligation; or

(ii) That the employment of the program participant has been terminated involuntarily for reasons unrelated to job performance.

(2) In determining whether compliance by a program participant with the terms of a service or repayment obligation imposes an extreme hardship, the Secretary may, on the basis of information and documentation as may be required, take into consideration the nature of the participant's personal problems and the extent to which these affect the participant's ability to perform the obligation.

(c) All requests for waivers must be submitted to the Secretary in writing.

(d) A program participant who is granted a waiver in accordance with this section will be notified by the Secretary in writing.

(e) Any obligation of a program participant for service or payment will be canceled upon the death of the program participant.

§ 3431.23 Service to Federal government in emergency situations.

(a) The Secretary may enter into agreements of 1 year duration with veterinarians who have service agreements for such veterinarians to provide services to the Federal Government in emergency situations, as determined by the Secretary, under terms and conditions specified in the agreement.

(b) Pursuant to a service agreement under this section, the Secretary shall pay an amount, in addition to the amount paid, as determined by the Secretary and specified in the agreement, of the principal and interest of qualifying educational loans of the veterinarians. This amount will be provided in the RFA.

(c) Agreements entered into under this paragraph shall include the following:

(1) A veterinarian shall not be required to serve more than 60 working days per year of the agreement.

(2) A veterinarian who provides service pursuant to the agreement shall receive a salary commensurate with the duties and shall be reimbursed for travel and per diem expenses as appropriate for the duration of the service.

§ 3431.24 Reporting requirements, monitoring, and close-out.

VMLRP participants will be required to submit periodic reports per the terms and conditions of their service agreements. In addition, the Secretary is responsible for ensuring that a VMLRP participant is complying with the terms and conditions of their service agreement, including any additional reporting or close-out requirements.

Done in Washington, DC, this 9th day of April 2010.

Dr. Meryl Broussard,

Interim Deputy Director, National Institute of Food and Agriculture.

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10 CFR Part 51

[NRC–2009–0269]

RIN 3150–AI27

Categorical Exclusions From Environmental Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations that describe the categories of actions which do not require an environmental review under the requirements of the National Environmental Policy Act of 1969 (NEPA) as the NRC has determined that such actions do not individually or cumulatively have a significant effect on the human environment. The amended regulations eliminate the need for the preparation of environmental assessments for NRC actions that are minor, administrative, or procedural in nature. The amendments do not change any requirements for licensees, but may provide for more time for NRC action on more substantial issues and/or speed up the process for review of the amendments.

DATES: This final rule is effective on April 19, 2010.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

- *Federal e-Rulemaking Portal:* Go to *http://www.regulations.gov* and search

for documents filed under Docket ID NRC–2008–0269. Address questions about NRC dockets to Carol Gallagher at 301–492–3668; e-mail *Carol.Gallagher@nrc.gov.*

• *NRC's Public Document Room (PDR):* The public may examine and may have copied for a fee publicly available document at the NRC's PDR, Public File Area O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available electronically at the NRC's electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–899–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.*

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SUPPLEMENTARY INFORMATION:

I. Background

NEPA requires Federal agencies to undertake an assessment of the environmental effects of their proposed actions prior to making a decision on whether to approve or disapprove of the proposed action. The NRC's NEPA regulations are contained in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

A. General Overview of Categorical Exclusion

There are three types of NEPA analyses: An environmental impact statement (EIS), an environmental assessment (EA), and a categorical exclusion. An EIS documents an agency's evaluation of the environmental impacts of a major Federal action significantly affecting the quality of the human environment. An EA is a concise, publicly available document that provides sufficient evidence and analysis for determining whether to prepare an EIS or make a finding of no significant impact (FONSI). If an EA supports a FONSI, the environmental review process is complete. If the EA reveals that the proposed action may have a significant effect on the human environment, the Federal agency then prepares an EIS. A categorical exclusion, in contrast, is a category of actions that the agency has determined not to have a significant effect, either individually or cumulatively, on the human environment. A categorical exclusion is established by rulemaking. Once it has established a categorical exclusion, the agency is not required to prepare an EA or EIS for any action that falls within the scope of the categorical exclusion, unless the agency finds, for any particular action, that there are special (*e.g.,* unique, unusual or controversial) circumstances that may have a significant effect on the human environment. Categorical exclusions streamline the NEPA process, saving time, effort, and resources.

B. NRC Categorical Exclusion Regulations

On July 18, 1974, the NRC published a final rule (39 FR 26279) that added 10 CFR Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," to the NRC regulations. This rulemaking listed four categorical exclusions. On March 12, 1984, the NRC published a final rule (49 FR 9352) revising and renaming 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions and Related Conforming Amendments." This final rule expanded the number of categorical exclusions from four to eighteen, and redesignated the section listing the NRC's approved categorical exclusions as 10 CFR 51.22, "Criterion for and identification of licensing and regulatory actions eligible for categorical exclusion." [1]

C. Amendments to NRC Categorical Exclusion Regulations

NRC has made 14 amendments to the categorical exclusions in § 51.22 since 1984. Ten of these amendments were minor, corrective, or conforming changes, and four were more substantive. All resulted from rulemaking efforts addressing other parts of NRC regulations. As a result of the 14 amendments, the list of categorical exclusions in § 51.22(c) increased from 18 to 23 categorical exclusions. The NRC's categorical exclusions include administrative, managerial, or organizational amendments to certain types of NRC regulations, licenses, and certificates; minor changes related to application filing procedures; and certain personnel and procurement activities.

D. Basis for Amendment of Categorical Exclusion Regulation

The NRC is amending the 10 CFR 51.22 categorical exclusions to reflect regulatory experience gained since the development of this regulation in March 1984. Prior to this amendment effort, there has been no comprehensive review and update of § 51.22. The amendments being adopted in this final rule are based, in part, on the Council on Environmental Quality (CEQ) September 2003 NEPA Task Force Report (Task Force Report) "Modernizing NEPA Implementation," *http://www.nepa.gov/ntf/report/pdftoc.html.* The Task Force Report notes that the development and updating of categorical exclusions by Federal agencies occurs infrequently and recommends that Federal agencies examine their categorical exclusion regulations to identify potential revisions that would eliminate unnecessary and costly EAs. It also provides recommendations for categorical exclusion development and revision.

The Task Force Report notes that in developing new or broadening existing categorical exclusions, a key issue is how to evaluate whether a proposed categorical exclusion is appropriate and how to support the determination that it describes a category of actions that do not individually or cumulatively have a significant effect on the human

[1] The section heading was revised to its current heading, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review," by a final rule published on July 3, 1989 (54 FR 27870).

environment. The Task Force Report recommends the use of information from past actions to establish the basis for the no significant effect determination. It further advises Federal agencies to evaluate past actions that occurred during a particular period to determine how often the NEPA analyses resulted in FONSIs for the category of actions being considered. The Task Force Report indicates that an adequate basis for developing new or broadening existing categorical exclusions exists if all the evaluated past actions resulted in FONSIs. It also provides that criteria for identifying new categorical exclusions should include: (1) Repetitive actions that do not individually or cumulatively have significant effects on the human environment; (2) actions that generally require limited environmental review; and (3) actions that are noncontroversial.

The amendments being adopted in this final rule are also based upon a review of NRC regulatory actions. As noted, the Task Force Report recommends that agencies evaluate past EA/FONSIs for particular categories of actions to develop new or broaden existing categorical exclusions. To comply with this recommendation, an NRC search of files for EA/FONSIs completed during the 20-year period from 1987 to 2007 was conducted. The search revealed that more than 1,500 actions resulted in EA/FONSIs. NRC conducted an in-depth review of the EA/FONSIs issued during the period 2003–2007. That review identified several recurring categories of regulatory actions that are not addressed in 10 CFR 51.22, and have no significant effect on the human environment, either individually or cumulatively. These categories of actions were considered in the amendments being adopted in this final rule.

II. Discussion

A. What Is a Categorical Exclusion?

The CEQ Task Force report defines the term "categorical exclusion" as "a category of actions that do not individually or cumulatively have a significant effect on the human environment and, therefore, preparing an EA or an EIS is not required unless extraordinary circumstances indicate otherwise." [2] If a certain type of regulatory action, such as the amendment of regulations, would not normally result in any significant effect upon the human environment, then it is unnecessary to spend time and effort to repeatedly document that fact. The Task Force Report's definition of a "categorical exclusion" also provides for "extraordinary circumstances" (essentially, the NRC equivalent of special circumstances) in which a normally excluded action may have a significant environmental effect, and thus require preparation of an EA or an EIS.

B. What Is NRC's Definition of Categorical Exclusion?

A "categorical exclusion" is defined in NRC's regulations in 10 CFR 51.14 as a "category of actions which do not individually or cumulatively have a significant effect on the human environment and which the Commission has found to have no such effect in accordance with procedures set out in § 51.22, and for which, therefore neither an environmental assessment nor an environmental impact statement is required." The NRC has determined that the categorical exclusions listed in 10 CFR 51.22 do not have a significant effect on the human environment.

C. How Should a Categorical Exclusion Be Applied?

Before applying a categorical exclusion to a proposed action, it should be determined whether there are any special circumstances that would potentially effect the human environment. If such special circumstances are, or are likely to be present, the NRC would then prepare an EA and, if necessary, an EIS. If special circumstances are not present, then the categorical exclusion may be applied and the NRC will satisfy its NEPA obligation for that proposed action. The determination of whether special circumstances are present is a matter of NRC discretion. The determination that special circumstances are not present will not require the preparation of any specific or additional documentation beyond the documentation normally prepared, if any, indicating that the categorical exclusion is being invoked for the proposed action.

D. What Action Is the NRC Taking?

The NRC is amending its list of categorical exclusions to clarify the scope of existing categories and to add new categories of actions that have been shown to have no significant effect on the human environment. For example, the provisions in § 51.22(c)(10) cover administrative and procedural changes to a license or permit. However, because of the ambiguity of the language in this provision, the NRC has prepared numerous EA/FONSIs for changes to a licensee's name, address, or telephone number. In addition, these amendments broaden the scope of the categorical exclusion that addresses decommissioning activities and adds categorical exclusions that address the awarding of education grants and the granting of exemptions from certain regulatory requirements.

The amendments to the categorical exclusion regulations will reduce inefficiencies and inconsistencies in the implementation of NRC's regulatory program. The amendments will eliminate the need to prepare unnecessary EAs for NRC regulatory actions that have no significant effect on the human environment. The amendments will also support the NRC's organizational objectives of ensuring that its actions are effective, efficient, realistic, and timely.

E. Who Would This Action Affect?

This amendment will not impose any new requirements on NRC licensees. It will ensure that review of licensees' amendment requests are completed by the NRC in a more efficient, effective, and timely manner, and will result in cost savings to the NRC and licensees. The amendments eliminate the need for the preparation of EA/FONSIs for actions that routinely have been shown to have no effect on the human environment, e.g., licensee requests concerning administrative, managerial, or organizational matters. For example, current ambiguities in the categorical exclusion regulations have created delays in licensee decisions when organizational name changes occur, because these decisions must await the completion of an EA/FONSI and publication in the **Federal Register** by the NRC.

III. Summary of Public Comments on the Proposed Rule

The proposed rule to amend the categorical exclusions in 10 CFR 51.22 was published on October 9, 2008 (73 FR 59540), with a 75-day comment period, which ended on December 23, 2009. The NRC received four comment submissions on the proposed rule. The commenters included a member of the public, one industry organization, and two State agencies. Copies of the public comments are available for review in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD, or *http://www.regulations.gov* under Docket ID NRC–2008–0269.

Analysis of Public Comments

1. *Comment.* The commenter, a member of the public, stated that there should never be exemptions from any environmental review. The comment

[2] CEQ regulations define the term "categorical exclusion" at 40 CFR 1508.4.

submission also included other comments that are beyond the scope of this rulemaking.

Response: Excluding categories of actions from environmental review, for which the agency has demonstrated that there will be no significant effect on the human environment, either individually or cumulatively, is an established, authorized NEPA practice. CEQ regulations expressly authorize and encourage the use of categorical exclusions by agencies to reduce "excessive paperwork." [3] According to the CEQ Task Force Report, CEQ "strongly discourages procedures that require additional paperwork to document that an activity has been categorically excluded." [4] The categorical exclusion process provides that if a certain type of regulatory action would not normally result in any significant effect upon the human environment, then it is unnecessary to spend time and effort to repeatedly document that fact.

Moreover, a categorical exclusion does not indicate the absence of an environmental review, but rather, that the agency has established a sufficient administrative record to show that the subject actions do not, either individually or cumulatively, have a significant effect on the human environment. Agencies establish sufficient administrative records to support categorical exclusions through the use of professional staff opinions, past NEPA records which show that the agency made a FONSI each time it considered the action, and the establishment of similar categorical exclusions by other agencies.[5]

With respect to those categorical exclusions established by this final rule, the NRC has established a sufficient administrative record, consisting of professional staff opinions and past NEPA records, which shows that these actions, either individually or cumulatively, do not result in a significant effect on the human environment. The statements of consideration for this final rule summarize the NRC's administrative record for each categorical exclusion. Also, under 10 CFR 51.22(b), in the event that special circumstances are present, the NRC retains discretion to prepare either an EA or EIS for an action that is otherwise categorically excluded.

2. *Comment:* The commenter, an industry organization, stated in its comment submission that it had reviewed the proposed revisions to 10 CFR Part 51 as described in the proposed rule and agreed that the categories of actions included therein have been shown to have no significant effect on the human environment, either individually or collectively, and should be excluded in accordance with NEPA and as defined in NRC regulations. The commenter supported issuance of a final rule to implement the proposed revisions set forth in the proposed rule.

Response: No response necessary.

3. *Comment:* The commenter, a State Department of Health, stated in its comment submission that it had reviewed the proposed revisions to 10 CFR Part 51 as described in the proposed rule and concurred with the recommendation that the NRC periodically examine its categorical exclusion regulations to identify potential revisions that would eliminate unnecessary and costly environmental assessments. The commenter also supported the concept that information from past actions be used to identify and modify or eliminate requirements that have no significant impact on humans or the environment. The commenter also agreed that the proposed revisions of the categorical exclusion regulations would minimize inefficiencies and inconsistencies in the implementation of NRC's regulatory program.

Response: No response necessary.

4. *Comment:* The commenter, a State Department of Environmental Conservation, raised concerns about the broadening of existing categorical exclusion 10 CFR 51.22(c)(9) to include power reactor licensee exemption requests from requirements concerning the installation or use of a facility component located within the restricted area of a Part 50 or 52 facility. The commenter stated that the fact that an EA and FONSI have been issued in the past is not sufficient justification to preclude all future requests for an exemption from Part 50 or 52 from a NEPA review. The commenter noted that Parts 50 and 52 regulate a broad range of activities at nuclear facilities and urged the NRC to take a hard look at the breadth of activities to be covered under the proposed revisions and to more carefully define the types of exception requests that qualify to be classified as a "categorical exclusion." The commenter stated that the proposed revision to 10 CFR 51.22(c)(9) had two critical defects: (1) That the public will be deprived of an opportunity to comment on an exemption from one or more of the enumerated requirements that potentially impacts public health, safety or welfare, and (2) important technical reviews will be foregone because a permit or license holder's request for exemption is erroneously considered insignificant. The commenter concludes that the amendment to 10 CFR 51.22(c)(9) is overly broad and warrants additional, more refined conditioning language to ensure that the above two critical defects are avoided.

Response: The commenter asserts that the fact that an EA and FONSI have been issued in the past is not sufficient justification to preclude all future requests for an exemption from Part 50 or 52 from a NEPA review under the amendment to 10 CFR 51.22(c)(9). As described in the CEQ Task Force Report, a consistent record of EA and FONSIs for a given category of actions is an acceptable basis to establish a categorical exclusion. In this regard, the NRC staff determined that during the 5-year period 2003 through 2007, over 50 EAs were prepared for licensee requests for exemptions, all of which resulted in a FONSI.

Moreover, an environmental review is not precluded by the establishment of this categorical exclusion. Before the categorical exclusion is applied, the NRC staff must find that the exemption request involves no significant hazards consideration, there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite, and there is no significant increase in individual or cumulative occupational radiation exposure.[6] The above findings would be made as part of the NRC's safety analysis for any licensee exemption request. If the NRC cannot make these findings, then the categorical exclusion will not apply and the NRC will prepare an EA, and if necessary, an EIS. Furthermore, the NRC can, in the event of special circumstances, as provided in 10 CFR 51.22(b), choose to prepare an EA or an EIS. Thus, the NRC concludes that the broadening of 10 CFR 51.22(c)(9) is appropriate.

The commenter urges the NRC to take a "hard look" at the breadth of activities to be covered under the amendment to 10 CFR 51.22(c)(9) in order to more carefully define the types of exemption requests that "truly qualify" to be classified as categorical exclusions. The amendment to this categorical exclusion, however, only covers exemption requests from a specified

[3] 40 CFR 1500.4(p). *See also* 40 CFR 1501.4(a)(2) (agency determines under its procedures whether action would be one that is normally subject to an EIS or is not subject to an EIS or EA and thus, a categorical exclusion); and 40 CFR 1508.4 (CEQ definition of categorical exclusion).

[4] CEQ, "The NEPA Task Force Report to the Council on Environmental Quality: Modernizing NEPA Implementation" (Task Force Report) 57–58 (2003).

[5] Task Force Report at 59.

[6] 10 CFR 51.22(c)(9)(i)–(iii).

subset of requirements under Part 50 or 52, namely, those exemption requests from Part 50 or 52 requirements related to the installation of or use of a facility component located within the restricted area, as defined by 10 CFR Part 20. The land covered by the restricted area is typically improved or otherwise previously disturbed and restricted to plant personnel or other screened individuals.

Given the 10 CFR 51.22(c)(9)(i)–(iii) criteria and the nature of the restricted area, it is extremely unlikely that granting any such exemption request would create any significant impact on the aquatic or terrestrial habitat in the vicinity of the plant, or to threatened, endangered, or protected species under the Endangered Species Act, or impacts to essential fish habitat covered by the Magnuson-Stevens Act. Similarly, it is extremely unlikely that there will be any impacts to socioeconomic, or historical and cultural resources. Thus, the NRC concludes that the amendment to 10 CFR 51.22(c)(9) is not overly broad, has sufficient protection, and is supported by an adequate administrative record.

The commenter further asserts that the public will be deprived of an opportunity to comment on an exemption from one or more of the enumerated requirements that potentially impact public health, safety, or welfare. In response, the NRC has concluded that broadening the categorical exclusion to include exemption requests will not have a significant effect on the human environment and will reduce unnecessary agency work. The NRC has further concluded that this amendment will not adversely impact public health and safety. This conclusion is based on the NRC's administrative record and the findings that must be made before the exemption can be approved, as required by 10 CFR 51.22(c)(9)(i)–(iii).

The commenter also asserts that important technical reviews will be foregone because a permit or license holder's request for exemption is erroneously considered insignificant. The application of the categorical exclusion to any exemption request, however, is separate and distinct from the safety analysis of the exemption request that will be conducted by the NRC staff. Absent the EA, the staff will still review the plant's procedures and technical specifications as well as evaluate the exemption request against the significance criteria in 10 CFR 51.22(c)(9)(i)–(iii).

5. *Comment:* The commenter, a State Department of Environmental Conservation, raised a concern about one of the new categorical exclusions, 10 CFR 51.22(c)(25), which covers exemption requests from administrative, managerial, or organizational requirements. Specifically, the commenter stated that the activities addressed in subparagraphs (C), (D), and (F) of 10 CFR 51.22(c)(vi)(25)[7] appear to be more safety-related than administrative, or that the requirements were more than administrative. Subparagraph (C) covered exemption requests from inspection or surveillance requirements; subparagraph (D) covered exemption requests from equipment servicing or maintenance requirements; and subparagraph (F) covered exemption requests from safeguards plans, including materials control, accounting, or other inventory requirements. The commenter urged the NRC to remove these exemption requests from the list of activities eligible for listing as a categorical exclusion.

Response: The NRC makes a distinction between conducting a safety analysis and conducting an environmental analysis. The NRC has determined that granting exemption requests from the types of requirements described in subparagraphs (C), (D), and (F) will not have a significant effect on the human environment. The commenter asserts that these requirements are more safety-related than administrative. The NRC will conduct a safety review and must make findings similar to those required by 10 CFR 51.22(c)(9). The proposed rule listed four findings, namely, that granting the exemption request would not result in a: (i) Significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (ii) significant increase in individual or cumulative public or occupational radiation exposure; (iii) significant construction impact; or (iv) there is no significant increase the potential for or consequences from radiological accidents.

In response to this comment, the final rule adds a fifth required finding that there will be no significant hazards consideration, set forth in this final rule as 10 CFR 51.22(c)(25)(i). In addition, the term "procedural" will be deleted from 10 CFR 51.22(c)(25)(vi)(I) (formerly subparagraph (c)(25)(v)(J) in the proposed rule) as the term "procedural" could be misconstrued in this context to include the requirement for licensees to implement procedures for substantive requirements. Thus, with these changes, the NRC concludes that the requirement to make these findings as part of its safety analysis provides adequate protection of public health and safety and as such, the revised categorical exclusion is appropriate.

[7] The paragraph in question was designated as 10 CFR 51.22(c)(25)(v) in the proposed rule.

IV. Discussion of Amendments by Section

A. Why Revise the Description of Categorical Exclusions in 10 CFR 51.22(a)?

This rule amends § 51.22(a) to clarify that the types of actions eligible for a categorical exclusion include "administrative" actions in addition to "licensing" and "regulatory" actions.

B. Why Revise the Categorical Exclusion in 10 CFR 51.22(c)(1) Which Addresses Amendments to 10 CFR Parts That Pertain Solely to Organizational, Administrative or Procedural Matters?

This rule amends § 51.22(c)(1) to include references to 10 CFR Parts that were inadvertently omitted. The 10 CFR Parts referenced in this section relate to matters regarding Commission organization, administration, or procedure. They serve the dual purpose of making information readily available to the public and of establishing administrative procedures for the orderly conduct of Commission business. The NRC has established that these types of regulatory actions do not individually or cumulatively have a significant effect on the human environment.

This amendment updates 10 CFR 51.22(c)(1) to include references to the following Commission organizational, administrative, or procedural requirements in the following 10 CFR Parts:

Part 5—Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance. This part is designed to eliminate (with certain exceptions) sex discrimination in any education program or activity receiving Federal financial assistance.

Part 12—Implementation of the Equal Access to Justice Act in Agency Proceedings. This part establishes regulatory requirements for awarding of attorney fees to eligible individuals and entities in certain administrative proceedings before the Commission.

Part 13—Program Fraud Civil Remedies. This part establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, false, fictitious, or fraudulent claims. It also specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties.

Part 15—Debt Collection Procedures. This part establishes administrative procedures for the Commission to collect the payment of debts owed to the United States Government in the form of money or property, unless a different procedure is specified in a statute, regulation, or contract.

Part 16—Salary Offset Procedures for Collecting Debts Owed by Federal Employees to the Federal Government. This part establishes procedures for the collection by administrative offset of a Federal employee's salary without his or her consent to satisfy certain debts owed to the Federal Government.

Part 26—Fitness for Duty Programs. This part prescribes requirements and standards for the establishment and maintenance of certain aspects of fitness-for-duty programs and procedures.

Part 160—Trespassing on Commission Property. This part provides for the protection and security of NRC facilities, installations, and properties from unauthorized entry and from unauthorized weapons or dangerous materials.

C. Why the Commission Has Chosen Not To Revise the Categorical Exclusion in 10 CFR 51.22(c)(2)

The proposed rule proposed broadening the scope of 10 CFR 51.22(c)(2) to include regulatory amendments that updated references, and to make other modifications to the language. Subsequent to the publication of the proposed rule, the NRC staff re-evaluated this proposed amendment and determined the proposed changes were overly broad, particularly regarding those amendments to the NRC regulations that incorporated by reference updates to American Society of Mechanical Engineers (ASME) or similar codes. For example, it was determined that certain code cases for Section II of the ASME Boiler and Pressure Vessel code, "Materials," could result in an alloy being altered to include a new material. Such new material, if in contact with the reactor coolant system, could become radioactively activated and could ultimately be released to the environment. Thus, the NRC staff concluded that such reference updates should be subject to an environmental review. The final rule will not amend 10 CFR 51.22(c)(2).

D. Why Revise the Categorical Exclusion in 10 CFR 51.22(c)(3) Which Addresses Amendments to Administrative, Organizational or Procedural Requirements Within Other 10 CFR Parts?

The final rule amends 10 CFR 51.22(c)(3) to delete the specific listing of 10 CFR Parts and to add a generic reference to reflect any part of CFR Chapter 10. This revision eliminates the need for changes due to new parts being added or deleted. As a result, efficiencies will be gained in the rulemaking process.

This amendment redesignates the existing subparagraph (iv) as subparagraph (v) and adds a new subparagraph (iv) to 10 CFR 51.22(c)(3) to expand the categorical exclusion to include amendments concerning education, training, experience, qualification, or other employment suitability requirements established in the regulations.

E. Why Revise Categorical Exclusion in 10 CFR 51.22(c)(9) Which Addresses Amendments to a Permit or License for a Reactor Under Parts 50 or 52?

The final rule amends 10 CFR 51.22(c)(9) to broaden the scope of the categorical exclusion to include the granting of a power reactor licensee exemption request from a requirement pertaining to the installation or use of a facility component located within the restricted area, as defined in 10 CFR Part 20. Under the previous provision, the granting of such an exemption request would not be covered by this categorical exclusion and therefore, would have required the preparation of an EA. The Commission has now determined that there is ample data in the form of EA and FONSIs to justify the categorical exclusion of the granting of these exemptions, provided that for each exemption request, the NRC first finds that the safety criteria set forth in 10 CFR 51.22(c)(9) are met (i.e., the exemption involves no significant hazards consideration, there is no significant change in the types of, or significant increase in the amounts of any effluents that may be released offsite, and there is no significant increase in individual or cumulative occupational radiation exposure). During the period 2003 through 2007, at least 50 EA/FONSIs resulted from licensee requests for such exemptions.

F. Why Revise the Categorical Exclusion in 10 CFR 51.22(c)(10) Which Addresses Administrative, Procedural, Organizational, or Editorial Changes to a Permit or License?

The final rule amends 10 CFR 51.22(c)(10) to delete the specific listing of 10 CFR Parts and to add a generic reference to cover any part of 10 CFR, Chapter 1. This revision eliminates the need for changes due to new parts being added or deleted. As a result, efficiencies are gained in the rulemaking process.

In addition, 10 CFR 51.22(c)(10) is revised to add new subparagraphs (iii), (iv), and (v) to clarify that changes to a license or permit that are administrative, organizational, or editorial in nature are not subject to environmental review. The NRC has conducted several EAs, each resulting in a FONSI, for minor administrative changes to licenses and permits because these actions were not specifically identified in 10 CFR 51.22(c). These types of amendments to a license or permit facilitate the orderly conduct of the licensee's business and ensure that information needed by the Commission to perform its regulatory functions is readily available. These amendments would also include the changing of references on licenses and other licensee documents (e.g., licensee's operational procedures) to reflect amendments to NRC regulations and updated NRC-approved guidance (*e.g.,* NUREG documents). Under the previous provision, the NRC was required to prepare EA and FONSIs for the following administrative actions:

(1) Amendments to reflect changes in ownership;

(2) Amendments to reflect organization name changes;

(3) Amendments to reflect corporate restructuring, including mergers;

(4) Amendments to licenses to reflect changes in references; and

(5) Amendments correcting typographical and editorial errors on licenses, permits, and associated technical specification documents.

The Commission has consistently determined that these types of amendments have no significant effect on the human environment.

G. Why Revise the Categorical Exclusion in 10 CFR 51.22(c)(20) Which Addresses Decommissioning of Sites?

The final rule adds a new subparagraph (iii) to 10 CFR 51.22(c)(20) to broaden the scope of the 10 CFR 51.22(c)(20) categorical exclusion to include Group 2 decommissioning activities. Decommissioning activities

are described in NRC's guidance, NUREG–1757, Vol. 1, Rev. 2, "Consolidated NMSS Decommissioning." NUREG–1757 divides decommissioning activities into seven decommissioning groups, Groups 1–7. Prior to this amendment, the 10 CFR 51.22(c)(20) categorical exclusion covered Group 1 decommissioning activities only. Group 2 decommissioning activities are those activities that involve the decommissioning of sites where licensed operations have been limited to the use of radioactive materials in such a manner that a decommissioning plan is not required by 10 CFR 30.36(g)(1), 40.42(g)(1) or 70.38(g)(1), and the NRC has determined that the facility meets the radiological criteria for unrestricted use in 10 CFR 20.1402, without further remediation or analysis.

Group 2 decommissioning activities cover:

(1) Facilities where the licensee possessed and used only sealed sources, but the most recent leak tests indicate that the sources leaked or leak tests are not available; or

(2) Facilities where the licensee used unsealed radioactive material and the licensee's survey demonstrated that levels of radiological contamination on building surfaces or surface soils meet the provisions for unrestricted use in 10 CFR 20.1402 by applying NRC-approved decommissioning screening criteria, and the licensee is not required to submit a decommissioning plan.

Group 2 decommissioning requests received by the NRC involve licensees who are authorized to possess and use sealed and/or unsealed radioactive materials with half-lives greater than 120 days. For example, the most common unsealed radioactive materials used by Group 2 licensees are tritium (H-3) and Carbon-14.

Normally, Group 2 licensees in the decommissioning process remediate their sites, as necessary, using their operating procedures. These licensees are required to keep records of material receipt, use, and disposal, enabling them to quantify past radiological material possession and use with a high degree of confidence. In order for the decommissioning action to meet Group 2 criteria, the licensee must maintain radiological survey records that characterize the residual radiological contamination levels present within the facilities and at their sites. In addition, Group 2 licensees must be able to demonstrate residual radiological contamination levels without more sophisticated survey procedures or dose modeling. These licensees are not required to have a decommissioning plan, but must demonstrate that their site meets the screening criteria of 10 CFR 20.1402.

In many cases, the NRC conducts confirmatory surveys during the licensee's decommissioning activities to verify the accuracy of the measuring techniques used to satisfy the requirements of 10 CFR 20.1402. The NRC uses a risk-informed process that assigns higher priority for conducting confirmatory surveys at sites that may pose a greater threat to the public health and safety. The results of this survey are used by the NRC to support a decision on whether to approve a licensee's request to terminate a license and release the site for unrestricted use.

Prior to this amendment, 10 CFR 51.22(c)(20) categorically excluded from further NRC environmental review those activities which are defined in NUREG–1757 as Group 1 decommissioning activities, namely, the decommissioning of sites where licensed operations had been limited to the use of small quantities of unsealed short-lived radioactive materials or radioactive materials in sealed sources, provided there is no evidence of leakage of radioactive material from these sealed sources. The 10 CFR 51.22(c)(20) decommissioning categorical exclusion was added with the promulgation of the license termination rule, "Radiological Criteria for License Termination" (July 21, 1997; 62 FR 39058). The license termination rule, codified at 10 CFR Part 20, Subpart E, established a dose-based radiological criterion of 25 mrem/yr in 10 CFR 20.1402 for the release of a decommissioned site for unrestricted use.

In establishing the decommissioning categorical exclusion, the Commission relied on the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination on NRC-Licensed Nuclear Facilities" (GEIS; NUREG–1496, Vol. 1). The GEIS concluded that with the use of "decay in storage" for the short-lived nuclides (those with a half-life of less than or equal to 120 days) and the time involved in submitting the information necessary to terminate a license, the activity of licensed material would reach sufficiently low levels such that decontamination of the building or of soils would not be needed.

However, the GEIS did not enable the Commission to determine that there would be no significant effect on the human environment from the use of unsealed radioactive materials with half-lives of more than 120 days. Specifically, the Commission determined that the unique conditions of each licensee facility and the specific uses of unsealed radioactive materials at each site prevented the environmental impacts from being analyzed on a generic basis. Accordingly, the Commission relied on the GEIS to satisfy its obligations under NEPA regarding decommissioning decisions on sites that meet the 25 mrem/y (0.25 mSv/yr) criterion for unrestricted use, but continued to require an EA for the decommissioning of any site on which unsealed radioactive materials with half-lives of more than 120 days are located. As such, based upon the 1997 Commission decision, EAs were performed for Group 2 decommissioning activities.

The Commission has now determined that there is ample data in the form of EA and FONSIs to justify the categorical exclusion of Group 2 decommissioning activities. The data shows that, during the period 2003 through 2007, each of the 73 EAs performed for a Group 2 decommissioning action resulted in a FONSI. Thus, subparagraph (iii) is added to 10 CFR 51.22(c)(20) to categorically exclude from further environmental review the decommissioning of sites where radioactive material has been used in such a manner that a decommissioning plan is not required based on 10 CFR 30.36(g)(1), 40.42(g)(1), or 70.38(g)(1) and the NRC has determined that the facility meets the radiological criteria for unrestricted use in 10 CFR 20.1402 without further remediation or analysis. If further remediation or analysis is needed to meet 10 CFR 20.1402, the decommissioning activity would be considered a Group 3 or higher decommissioning activity in accordance with NUREG–1757, and would not be covered by this categorical exclusion.

H. Why Add a Categorical Exclusion in 10 CFR 51.22(c)(24) Which Addresses the Awarding of Education Grants?

The final rule adds a new categorical exclusion, 10 CFR 51.22(c)(24), which categorically excludes the issuance of grants, by the NRC, to institutions of higher education in the United States, for scholarships, fellowships, and stipends in science, engineering, or another field of study that the NRC determines is in a critical skill area related to its regulatory mission. These grants may also support faculty or curriculum development as well as other domestic educational, technical assistance, or training programs (including those of trade schools) in such fields. This categorical exclusion covers those actions that are specifically geared toward the development of teaching and educational programs in the nuclear field. The purpose of the

grant program is to foster a work force capable of supporting the safe design, construction, operation, and regulation of nuclear facilities, and the safe handling of nuclear materials.

Sections 31.b.(2) and 243 of the Atomic Energy Act of 1954, as amended, constitute the statutory basis of this grants program. Section 243 authorizes the creation of a scholarship and fellowship program to fund scholarships, fellowships, and stipends for the study of science, engineering, or another field of study that the NRC determines is a critical skill area related to its regulatory mission, to support faculty and curricular development in such fields, and to support other domestic educational, technical assistance, or training programs (including those of trade schools) in such fields. Section 31.b.(2) authorizes the NRC to provide grants, loans, cooperative agreements, contracts, and equipment to institutions of higher education to support courses, studies, training, curricula, and disciplines pertaining to nuclear safety, security, or environmental protection, or any other field that the NRC determines to be critical to its regulatory mission.

This new categorical exclusion covers actions that the NRC has determined to be administrative in nature. The categorical exclusion contains prescriptive language (10 CFR 51.22(c)(24)(i)–(iv)) that limits its application to only those grants that will not have a significant effect on the human environment. In this regard, the categorical exclusion does not apply to those grants that may be used to directly support the construction of facilities, field work (except field work which only involves noninvasive or non-harmful techniques), or the testing and release of radioactive material. Furthermore, the categorical exclusion would not apply to those grants that would directly support any action that would lead to a major disturbance of the environment brought about by blasting, drilling, excavating, or other means.

I. Why Add a Categorical Exclusion in 10 CFR 51.22(c)(25) Which Addresses the Granting of Exemptions From Regulatory Requirements?

The final rule adds a new categorical exclusion, 10 CFR 51.22(c)(25), which addresses the granting of licensee exemption requests from certain regulatory requirements. Various NRC regulations allow for the granting of specific exemptions from NRC regulations.[8] Before an exemption may be granted, the NRC must satisfy certain criteria, namely, it must make findings that the exemption is "authorized by law," "will not endanger life or property or the common defense and security," and is "otherwise in the public interest." In the case of Part 50 and 52 exemptions, the exemption request must meet additional criteria.[9] The NRC thoroughly evaluates each exemption request under these provisions, and only those exemption requests that meet these provisional criteria are granted.

Prior to this final rule, 10 CFR 51.22 did not provide a categorical exclusion for the granting of exemption requests from administrative, managerial, or organizational regulatory requirements that will not have a significant effect on the human environment. The NRC has found that the majority of the exemptions it grants are administrative or otherwise minor in nature and do not trigger any of the significance criteria that are required findings under other categorical exclusions, such as 10 CFR 51.22(c)(9)(i)–(iii). The NRC has prepared numerous EAs, each resulting in a FONSI, to support the granting of such exemption requests.

This categorical exclusion contains prescriptive criteria that limit its application to only those exemptions that will not have a significant effect on the human environment. The categorical exclusion only applies to those exemption requests that meet all of the criteria enumerated in 10 CFR 51.22(c)(25)(i)–(vi). Thus, the requirements from which the exemption is sought must be one of those listed in 10 CFR 51.22(c)(25)(vi). In addition, the granting of the exemption request cannot result in any:

(1) Significant hazards consideration;

(2) Significant change in the types or significant increase in the amounts of any effluents that may be released offsite;

(3) Significant increase in individual or cumulative public or occupational radiation exposure;

(4) Significant construction impact; or

(5) Significant increase in the potential for or consequences from radiological accidents.

The NRC has found that granting exemptions for the types of requirements listed in subparagraphs 51.22(c)(25)(vi)(A)–(I) are categories of actions that normally do not result in any significant effect, either individually or cumulatively, on the human environment. Thus, in order for the categorical exclusion to be applicable to a specific exemption request, the NRC staff must first make the safety findings described in 10 CFR 51.22(c)(25)(i)–(v) and then determine that the requirement is of a type listed in 10 CFR 51.22(c)(25)(vi).

V. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as a Compatibility Category "NRC." The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State. NEPA applies only to Federal agencies. This final rule will not have any impact on Agreement States' regulations. Therefore, Agreement States will not need to make conforming changes to their regulations.

VI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. The NRC is amending 10 CFR 51.22, the NRC's list of categories of actions that the NRC has determined to have no significant effect on the human environment. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

VII. Finding of No Significant Environmental Impact: Availability

Under NEPA and the NRC regulations in Subpart A of 10 CFR Part 51, the NRC has determined that this rule would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an EIS is not required. The NRC prepared an EA and, on the basis of this EA, has made a FONSI. These amendments are based upon NRC review of environmental assessments conducted during the period 2003–2007 that have consistently resulted in FONSIs. The amendments to the categorical exclusions are administrative, procedural, or otherwise

[8] *E.g.,* 10 CFR 20.2301, 30.11, 40.14, 50.12, 52.7, 70.17, 72.7, and 76.23.

[9] 10 CFR 50.12(a)(2); 10 CFR 52.7.

minor in nature (*e.g.,* no significant increases in the amounts of any effluents that may be released offsite).

The NRC sent a copy of the EA and the proposed rule to every State Liaison Officer and requested their comments on the EA. Two State comment submissions were received. The States' comments and the NRC responses thereto are described in the Analysis of Public Comments section of this final rule. The EA may be examined at the NRC Public Document Room, 11555 Rockville Pike, Room O–1F23, Rockville, MD 20852.

VIII. Paperwork Reduction Act Statement

This rule does not contain information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IX. Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

X. Regulatory Analysis

This rule is anticipated to be cost-effective. It would eliminate the need to prepare EAs for actions that have no significant effect on the human environment, and would eliminate the delays associated with the preparation of these documents. A regulatory analysis is not required because this rulemaking does not impose any new requirements on NRC licensees.

XI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities.

XII. Backfit Analysis

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this rule because this amendment would not involve any provisions that would impose backfits as defined in 10 CFR Chapter I. Therefore, a backfit analysis is not required.

XIII. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget.

List of Subjects in Part 51

Administrative practice and procedure, Environmental impact statement, Hazardous waste, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

■ For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC proposes to adopt the following amendments to 10 CFR Part 51:

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

■ 1. The authority citation for Part 51 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953, (42 U.S.C. 2201, 2297f); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Subpart A also issued under National Environmental Policy Act of 1969, secs. 102, 104, 105, 83 Stat. 853–854, as amended (42 U.S.C. 4332, 4334, 4335); and Pub. L. 95–604, Title II, 92 Stat. 3033–3041; and sec. 193, Pub. L. 101–575, 104 Stat. 2835 (42 U.S.C. 2243). Sections 51.20, 51.30, 51.60, 51.80, and 51.97 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241, and sec. 148, Pub. L. 100–203, 101 Stat. 1330–223 (42 U.S.C. 10155, 10161, 10168). Section 51.22 also issued under sec. 274, 73 Stat. 688, as amended by 92 Stat. 3036–3038 (42 U.S.C. 2021) and under Nuclear Waste Policy Act of 1982, sec 121, 96 Stat. 2228 (42 U.S.C. 10141). Sections 51.43, 51.67, and 51.109 also under Nuclear Waste Policy Act of 1982, sec 114(f), 96 Stat. 2216, as amended (42 U.S.C. 10134(f)).

■ 2. Amend § 51.22 by revising paragraphs (a), (c)(1), (c)(3), (c)(9), (c)(10), and (c)(20) and adding paragraphs (c)(24) and (c)(25) to read as follows:

§ 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

(a) Licensing, regulatory, and administrative actions eligible for categorical exclusion shall meet the following criterion: The action belongs to a category of actions which the Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment.

* * * * *

(c) * * *

(1) Amendments to Parts 1, 2, 4, 5, 7, 8, 9, 10, 11, 12, 13, 15, 16, 19, 21, 25, 26, 55, 75, 95, 110, 140, 150, 160, 170, or 171 of this chapter, and actions on petitions for rulemaking relating to Parts 1, 2, 4, 5, 7, 9, 10, 11, 12, 13, 14, 15, 16, 19, 21, 25, 26, 55, 75, 95, 110, 140, 150, 160, 170, or 171 of this chapter.

* * * * *

(3) Amendments to any part in this chapter which relate to—

(i) Procedures for filing and reviewing applications for licenses or construction permits or early site permits or other forms of permission or for amendments to or renewals of licenses or construction permits or early site permits or other forms of permission;

(ii) Recordkeeping requirements;

(iii) Reporting requirements;

(iv) Education, training, experience, qualification or other employment suitability requirements or

(v) Actions on petitions for rulemaking relating to these amendments.

* * * * *

(9) Issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter, which changes a requirement, or grants an exemption from any such requirement, with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter, or which changes an inspection or a surveillance requirement, provided that:

(i) The amendment or exemption involves no significant hazards consideration;

(ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and

(iii) There is no significant increase in individual or cumulative occupational radiation exposure.

(10) Issuance of an amendment to a permit or license issued under this chapter which—

(i) Changes surety, insurance and/or indemnity requirements;

(ii) Changes recordkeeping, reporting, or administrative procedures or requirements;

(iii) Changes the licensee's or permit holder's name, phone number, business or e-mail address;

(iv) Changes the name, position, or title of an officer of the licensee or permit holder, including but not limited to, the radiation safety officer or quality assurance manager; or

(v) Changes the format of the license or permit or otherwise makes editorial, corrective or other minor revisions, including the updating of NRC approved references.

* * * * *

(20) Decommissioning of sites where licensed operations have been limited to the use of—

(i) Small quantities of short-lived radioactive materials;

(ii) Radioactive materials in sealed sources, provided there is no evidence of leakage of radioactive material from these sealed sources; or

(iii) Radioactive materials in such a manner that a decommissioning plan is not required by 10 CFR 30.36(g)(1), 40.42(g)(1), or 70.38(g)(1), and the NRC has determined that the facility meets the radiological criteria for unrestricted use in 10 CFR 20.1402 without further remediation or analysis.

* * * * *

(24) Grants to institutions of higher education in the United States, to fund scholarships, fellowships, and stipends for the study of science, engineering, or another field of study that the NRC determines is in a critical skill area related to its regulatory mission, to support faculty and curricular development in such fields, and to support other domestic educational, technical assistance, or training programs (including those of trade schools) in such fields, except to the extent that such grants or programs include activities directly affecting the environment, such as:

(i) The construction of facilities;

(ii) A major disturbance brought about by blasting, drilling, excavating or other means;

(iii) Field work, except that which only involves noninvasive or non-harmful techniques such as taking water or soil samples or collecting non-protected species of flora and fauna; or

(iv) The release of radioactive material.

(25) Granting of an exemption from the requirements of any regulation of this chapter, provided that—

(i) There is no significant hazards consideration;

(ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite;

(iii) There is no significant increase in individual or cumulative public or occupational radiation exposure;

(iv) There is no significant construction impact;

(v) There is no significant increase in the potential for or consequences from radiological accidents; and

(vi) The requirements from which an exemption is sought involve:

(A) Recordkeeping requirements;

(B) Reporting requirements;

(C) Inspection or surveillance requirements;

(D) Equipment servicing or maintenance scheduling requirements;

(E) Education, training, experience, qualification, requalification or other employment suitability requirements;

(F) Safeguard plans, and materials control and accounting inventory scheduling requirements;

(G) Scheduling requirements;

(H) Surety, insurance or indemnity requirements; or

(I) Other requirements of an administrative, managerial, or organizational nature.

Dated at Rockville, Maryland, this 13th day of April 2010.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2010–8921 Filed 4–16–10; 8:45 am]

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FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 370

RIN 3064–AD37

Amendment of the Temporary Liquidity Guarantee Program To Extend the Transaction Account Guarantee Program With Opportunity To Opt Out

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Interim Rule with request for comments.

SUMMARY: The FDIC is issuing this Interim Rule to amend the Transaction Account Guarantee (TAG) component of the Temporary Liquidity Guarantee Program (TLGP) by providing an 6-month extension of the TAG program for insured depository institutions (IDIs) currently participating in the TAG program, with the possibility of an additional 12-month extension of the program without further rulemaking, upon a determination by the FDIC's Board of Directors (Board) that continuing economic difficulties warrant a continued extension. By virtue of this Interim Rule, the TAG program will be extended through December 31, 2010, with the possibility of an additional 12-month extension through December 31, 2011. In addition, while the Interim Rule presents no changes in the amount of the assessment for an IDI's continued participation in the TAG, it modifies the assessment basis for calculating the current risk-based assessments to one based on average daily balances in the TAG-related accounts. Further, the Interim Rule requires IDIs participating in the TAG program that offer NOW accounts covered by the program to reduce the interest rate on such accounts to a rate no higher than 0.25 percent and to commit to maintain that rate for the duration of the TAG extension in order for those NOW accounts to remain eligible for the FDIC's continued guarantee.

DATES: The Interim Rule becomes effective on April 19, 2010. Comments on the Interim Rule must be received by the FDIC no later than May 19, 2010.

ADDRESSES: You may submit comments on the Interim Rule, by any of the following methods:

- *Agency Web Site: http://www.FDIC.gov/regulations/laws/federal/notices.html.* Follow instructions for submitting comments on the Agency Web Site.
- *E-mail: Comments@FDIC.gov.* Include RIN # 3064–AD37 on the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.

Instructions: All comments received will be posted generally without change to *http://www.fdic.gov/regulations/laws/federal/final.html,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: A. Ann Johnson, Counsel, Legal Division, (202) 898–3573 or *aajohnson@fdic.gov;* Robert C. Fick, Counsel, Legal Division, (202) 898–8962 or *rfick@fdic.gov;* Julia E. Paris, Senior Attorney, Legal Division, (202) 898–3821 or *jparis@fdic.gov;* Lisa D Arquette, Associate Director, Division of Supervision and Consumer Protection, (202) 898–8633 or *larquette@fdic.gov;* Donna Saulnier, Manager, Assessment Policy Section, Division of Finance, (703) 562–6167 or *dsaulnier@fdic.gov;* or Rose Kushmeider, Acting Chief, Banking and Regulatory Policy Section, Division of Insurance and Research, (202) 898–3861 or *rkushmeider@fdic.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In October 2008, the FDIC adopted the TLGP following a determination of

systemic risk by the Secretary of the Treasury (after consultation with the President) that was supported by recommendations from the FDIC and the Board of Governors of the Federal Reserve System (Federal Reserve).[1] The TLGP is part of an ongoing and coordinated effort by the FDIC, the U.S. Department of the Treasury, and the Federal Reserve to address unprecedented disruptions in the financial markets and preserve confidence in the American economy.

The FDIC's October 2008 interim rule provided the blueprint for the TLGP.[2] The TLGP comprises two distinct components: The Debt Guarantee Program (DGP), pursuant to which the FDIC guarantees certain senior unsecured debt issued by entities participating in the TLGP; and the TAG program, pursuant to which the FDIC guarantees all funds held at participating IDIs (beyond the standard maximum deposit insurance limit) in qualifying noninterest-bearing transaction accounts.

The DGP addressed the acute needs of banks to obtain funding by permitting participating entities to issue FDIC-guaranteed senior unsecured debt until June 30, 2009, with the FDIC's guarantee for such debt to expire on the earlier of the maturity or conversion of the debt (for mandatory convertible debt) or June 30, 2012.[3] In order to reduce market disruption at the conclusion of the DGP and to facilitate the orderly phase-out of the program, the FDIC's Board, in March 2009, adopted another interim rule that, among other things, provided for a limited four-month extension for the issuance of senior unsecured debt under the DGP.[4] At the same time, the FDIC extended the expiration of the guarantee period from June 30, 2012, until December 31, 2012.[5] The DGP component of the TLGP has served a vital role in helping to restore market-based liquidity and confidence in the financial market.[6]

The TAG component of the TLGP was developed, in part, to address concerns that a large number of account holders might withdraw their uninsured account balances from IDIs due to then-prevailing economic uncertainties. Such withdrawals could have further destabilized financial markets and impaired the funding structure of smaller banks that rely on deposits as a primary source of funding while also negatively affecting other institutions that had relationships with these banks.[7] In designing the TAG program, the FDIC sought to improve public confidence and to encourage depositors to maintain their transaction account balances at IDIs participating in the TAG program.

In response to comments received by the FDIC following publication of the October 2008 interim rule, the FDIC expanded the TAG program to cover, among other accounts, "negotiable order of withdrawal," or NOW accounts, with interest rates no higher than 0.50 percent if the IDI offering the account committed to maintain that interest rate through December 31, 2009.[8] If an IDI offering NOW accounts with an interest rate in excess of 0.50 percent committed to reduce the rate to 0.50 percent or less by January 1, 2009, and to maintain that rate for the duration of the program, its NOW account would be considered eligible for the FDIC's TAG guarantee.[9]

The TAG program was originally set to expire on December 31, 2009.[10] The FDIC recognized that the TAG program was contributing significantly to improvements in the financial sector, but also noted that many parts of the country were still suffering from the effects of economic turmoil. As a result, on August 26, 2009, following a public notice and comment period,[11] the FDIC issued a final rule that extended the TAG program through June 30, 2010.[12]

The initial TAG extension included an increased assessment rate designed to offset the potential losses associated with the FDIC's guarantee. Prior to the extension, the fee for participating IDIs was a flat rate of 0.10 percent annually on all amounts in eligible TAG accounts not covered by regular deposit insurance. Beginning on January 1, 2010, the fee for continued participation in the TAG was raised and the basis changed to reflect an IDI's risk profile, ranging from 15 basis points to up to 25 basis points. The rule provided participating IDIs with a second opportunity to opt out of the TAG program.[13] The initial TAG extension also required participating IDIs to extend their commitment to maintain interest rates on NOW account at no higher than 0.50 percent during the extended TAG program.[14]

In extending the TAG program through June 30, 2010, the FDIC reiterated its belief that the country was experiencing overall improved economic conditions and that it had made progress toward a stable, fully functioning financial marketplace.[15] Yet the FDIC cautioned that this progress could be impeded or even undone by terminating the TAG program too quickly. As such, the FDIC deemed its initial extension of the TAG an appropriate step to a gradual phase out the program.[16]

II. Rationale for Extending the TAG Program

Since its inception, the TAG program has been an important source of stability for many banks with large transaction account balances. Currently, nearly 6,400 insured depository institutions, representing approximately 80 percent of all IDIs, continue to participate in the TAG program and to benefit from the guarantee provided by the FDIC. These institutions held an estimated $340 billion of deposits in accounts currently subject to the FDIC's guarantee as of the end of 2009. Of these, $266 billion represented amounts above the insured deposit limit and guaranteed by the FDIC through its TAG program. Among the current participants in the program, the average TAG account size was about $1.15 million. About 550 institutions relied on TAG accounts to fund 10 percent or more of their assets. In this challenging banking environment, smaller IDIs have continued to find the TAG program especially beneficial.

While the immediate financial crisis that led to the creation of the TLGP in October 2008 has abated, it was followed by an intensification of the recession that began in late 2007 and which continues to pressure local communities across the country. At the same time, the financial distress that emerged in 2008 has spread from large, systemically important banks to banks of all sizes, particularly in regions

[1] See Section 13(c)(4)(G) of the Federal Deposit Insurance Act (FDI Act), 12 U.S.C. 1823(c)(4)(G). The determination of systemic risk authorized the FDIC to take actions to avoid or mitigate serious adverse effects on economic conditions or financial stability, and the FDIC implemented the TLGP in response.

[2] 73 FR 64179 (Oct. 29, 2008). This Interim Rule was followed by a Final Rule, published in the **Federal Register** on November 26, 2008. 73 FR 72244 (Nov. 26, 2008).

[3] *Id.* at 64181–64182.

[4] 74 FR 12078 (Mar. 23, 2009). This Interim Rule was finalized and a Final Rule was published in the **Federal Register** on June 3, 2009. 74 FR 26521 (June 3, 2009).

[5] 74 FR 12078, 12080.

[6] On September 16, 2009, the FDIC published for comment alternative proposals for winding down the DGP component of the TLGP. Ultimately, the FDIC issued a final rule terminating the DGP as of October 31, 2009, and establishing a limited, six-month emergency guarantee facility. 74 FR 54743 (Oct. 23, 2009).

[7] 73 FR 64182–64183.

[8] 73 FR 72244, 72262 (Nov. 26, 2008).

[9] *Id.*

[10] 73 FR 64179, 64182 (Oct. 29, 2008).

[11] 74 FR 31217 (June 30, 2009).

[12] 74 FR 45093 (Sept. 1, 2009).

[13] *Id.*

[14] 74 FR 45098.

[15] 74 FR 45095.

[16] *Id.*

suffering from ongoing economic turmoil.

Since the establishment of the TLGP, there have been 187 bank and thrift failures, and the number of "problem" institutions has increased to 702, representing $403 billion in total assets, as of year-end 2009. Weaknesses facing community banks have intensified as the lingering consequences of the 2008 financial crisis and the recession place continued pressure on earnings and asset quality. In 2009, community banks experienced an aggregate $104 million loss, their first annual loss on record. Community banks increased their provisions for loan and lease losses to $5.1 billion during the fourth quarter of 2009, the highest level on record. The effects of the financial crisis and recession are expected to persist for some time, especially as the magnitude of economic distress facing local markets places continued pressure on asset quality and earnings, with the potential for undermining the stability of the banking organizations that serve these markets.

Although the condition of IDIs as a whole has deteriorated since the establishment of the TLGP, the TAG program has lessened some of their distress by enabling them to retain longstanding customer transaction relationships, such as payroll accounts from municipalities and small businesses. These deposits have significantly improved the funding situation of IDIs and allowed them to continue making investments in the communities they serve. Over 70 percent of industry assets were funded by deposits as of fourth quarter 2009, up from 65 percent a year ago. This increased reliance on deposit funding highlights the importance of the TAG program.

Based on these economic factors, the FDIC has concluded that allowing the TAG to expire on June 30, 2010, could negatively affect the banking system at a time when many IDIs continue to experience stressful economic and financial conditions. The FDIC is concerned that allowing the TAG program to expire in the current environment could cause a number of community banks to experience deposit withdrawals from their large transaction accounts and risk needless liquidity failures. To the extent IDIs are able to replace these deposits with brokered deposits or secured borrowings, their overall liquidity risk profile would increase going forward. However, the loss of longstanding large depositor relationships would negatively affect IDIs' deposit franchise values to an acquirer in the event of a failure, thus increasing the FDIC's resolution costs.

By extending the TAG program beyond its current program termination date of June 30, 2010, the FDIC seeks to maintain stability for IDIs and to promote a continuing and sustainable economic recovery throughout the country. Specifically, the FDIC anticipates that its extended guarantee of noninterest-bearing transaction accounts may provide participating institutions with a continued stable funding source. Moreover, recognizing the gap between funding costs of large and small banks,[17] the FDIC believes that a continuation of its TAG program will help maintain community banks' ability to compete for and secure low-cost large deposits, thereby preserving deposit franchise value and supporting the rebuilding of earnings and capital.

In providing for a six-month extension of the TAG program and for an additional 12-month extension without further rulemaking, if the Board concludes that such extension is warranted, the FDIC endeavors to avoid liquidity failures that may be indirectly precipitated by deposit migrations potentially caused by letting the TAG program expire on June 30, 2010. In most cases, liquidity failures are more costly for the FDIC to resolve as there is little time to market the institution. This leads to fewer and less informed bidders who will reduce the value of their proposals to compensate for the uncertainty in the transaction. Bidders are more reluctant to enter into transactions that transfer high-risk assets without having the time to conduct due diligence; this will result in more assets being retained by the FDIC, as receiver for failed IDIs. In addition, the loss of large balance transaction accounts that may leave the IDIs in the absence of the TAG program extension will reduce franchise values and make it more difficult for all-deposit resolution transactions to satisfy the least cost test. Finally, the diminution of deposit franchises may lead to more deposit payouts, which are expensive and consume large amounts of FDIC resources. For these reasons, extending the TAG is mission-critical for the FDIC, as steward of the DIF.

As the effects of the financial crisis and the recession continue to unfold, the FDIC remains committed to its primary goal of promoting confidence and stability in the banking system. The TAG program provides businesses and other large depositors with complete assurance that qualifying noninterest-bearing transaction accounts are fully guaranteed in participating IDIs. This, in turn, contributes to a more stable operating environment in which business activities may continue to normalize.

Moreover, the FDIC has received support from some industry participants for extending the program. These stakeholders have commented that the TAG program has had a positive and stabilizing effect on the banking industry and public confidence; terminating the program on June 30, 2010, would be premature given the delicate state of the nation's financial recovery. They further note that the TAG program benefits small businesses by guaranteeing payroll accounts and increasing the amount of funding available to make loans. Community banks are key providers of credit to small businesses, which have historically made significant contributions to new job growth and the overall strengthening of the economy. Thus, community bankers argue that extending the TAG program would provide them with an important source of liquidity necessary to continue providing credit to small businesses and creditworthy borrowers.

III. Authority To Extend TAG Program

The amendment to the TAG provided under the Interim Rule is based on the authority for the establishment of the TLGP, including the determination of systemic risk made in October 2008, pursuant to section 13(c)(4)(G) of the FDI Act.[18] A systemic risk determination authorizes the FDIC to not only take actions necessary at that time to avoid or mitigate serious adverse effects on economic conditions or financial stability, but also to continue to take such action as necessary in the future where the economic conditions and threats to financial stability that first gave rise to the determination persist or have shifted to adversely affect other sections of the banking industry.[19] The extension of the TAG component of the TLGP provided for in this Interim Rule represents a continuation of the previously authorized action by the FDIC to mitigate the continuing adverse effects, discussed in the preceding section, from the financial crisis and the recession by

[17] At year-end 2007, the average cost of interest-bearing domestic deposits at banks with over $100 billion in total assets was 35 basis points lower than at banks with under $1 billion in total assts. At the end of the second quarter 2008, this difference increased to 64 basis points. By year-end 2009, the spread was 107 basis points.

[18] 12 U.S.C. 1823(c)(4)(G).

[19] *See id.; see also Senior Unsecured Creditors' Comm. of First Republic Bank Corp.* v. *F.D.I.C.,* 749 F. Supp. 758, 768 (N.D. Tex. 1990).

providing additional stable funding for IDIs.

IV. The Interim Rule

A. Extension of the TAG Program for Participating IDIs

The TAG program currently expires on June 30, 2010. This Interim Rule extends the termination of the TAG program for six months, through December 31, 2010, with the possibility of an additional 12-month extension, through December 31, 2011, without further rulemaking, at the discretion of the Board upon a finding of a continuing need for the TAG program. If the Board determines that an additional 12-month extension of the TAG program is warranted, an announcement to that effect will be made by the FDIC no later than October 29, 2010. The FDIC believes that extending the TAG program will assist participating IDIs in successfully weathering the nation's continuing financial distress and in ensuring a more sustainable economic recovery.

B. No Increased Fee for Continued Participation in the Extended TAG Program

Under the current rule, the TAG program provides for a tiered-pricing assessment, ranging from 15 to 25 basis points based on an institution's deposit insurance assessment risk category. The FDIC believes that maintaining the current tiered pricing for the TAG program will enable most participating IDIs to remain in the program, thereby providing a greater positive stimulus to the nation's economic recovery. The FDIC believes that increasing the assessment for participating IDIs at this time would frustrate the overall goal of the extension of the TAG program and could further pressure the liquidity posture of participating IDIs.

Although costs from the TAG program will have exceeded revenues collected under the program through June 30, 2010, no increase in fees is being proposed for the extension of the TAG program under this Interim Rule. The FDIC estimates that projected revenues from assessments under a six-month extension in the TAG program could cover projected costs for the duration of the extension, but will more likely show a small loss under reasonable assumptions regarding continued participation in the program. In making our estimates, the FDIC expects that some IDIs will opt out of the TAG program and that participating IDIs will maintain, but not significantly increase, the amount of deposits in transaction accounts that are subject to the FDIC's guarantee.

This Interim Rule provides that the Board may determine that an additional extension of the TAG through December 31, 2011, may be warranted without further rulemaking. FDIC estimates for this period assume some improvement in the outlook for the banking industry and consequently indicate that projected revenues could cover, and possibly exceed, projected costs without a change in fee structure. As above, FDIC estimates were made using reasonable assumptions regarding continued participation in the program. However, projections beyond six months are always more problematic.

While the FDIC made reasonable assumptions regarding the costs that could be incurred during the 6-month extension and during a possible additional 12-month extension, under more severe, yet plausible, assumptions net losses under the TAG program could be greater. However, the FDIC does not believe that the losses would be so extreme under either extension as to cause the TLGP overall to experience a net loss. In fact, the FDIC believes it is reasonable to expect that the 6-month extension provided in this Interim Rule will result in only a slight loss and that if an additional 12-month extension is ultimately adopted, the TAG program for the two extension periods would be revenue neutral. Regardless of the ultimate duration of the program and even under the most severe loss estimates, the FDIC expects the TLGP will remain a profitable program. Accordingly, the Interim Rule does not increase the current tiered-assessment structure.

To prevent unanticipated risks to the DIF, the FDIC reminds participating IDIs to exercise prudent marketing of TAG accounts that qualify for the FDIC's guarantee and to continue to exercise risk-management principles applicable to an IDI's existing business plan. Because of the temporary nature of the TAG program, participating IDIs should not use the extension period to aggressively market or grow their TAG-related accounts.

C. Change in Basis for Reporting for Assessment Purposes

Participating IDIs currently report the total dollar amount and the total number of TAG-qualifying noninterest-bearing transaction accounts as of the end of the calendar quarter. By the very nature of these transaction accounts, the account balances are volatile, fluctuating greatly on any given day due to the operational nature of the deposits, such as for payrolls, and withdrawals made by typical business customers. Currently, the TAG total amounts and accounts are reported on the IDI's Report of Condition or Thrift Report.

In order to monitor and assess fees based upon the ongoing risk exposure of the DIF, the Interim Rule provides that IDIs that do not opt out of the TAG program under the mechanism described in Paragraph E, below, will be required to report their TAG amounts as average daily balance amounts. Under the Interim Rule, beginning with the September 30, 2010, report date for the Report of Condition or Thrift Financial Report, the total dollar amount of TAG-qualifying accounts and the total number of accounts must be reported as an average daily balance. This will cover the period from July 1 through September 30, 2010. The amounts to be reported as daily averages are the total dollar amount of the noninterest-bearing transactions accounts, as defined in 12 CFR 370.2(h), of more than $250,000 for each calendar day during the quarter divided by the number of calendar days in the quarter. For days that an office of the reporting institution is closed (e.g., Saturdays, Sundays, or holidays), the amounts outstanding from the previous business day would be used. The total number of accounts to be reported should be calculated on the same basis. Documentation supporting the amounts used in the calculation of the average daily balance amounts must be retained and be readily available upon request by the FDIC or the IDI's primary Federal regulator. In addition, all IDIs that do not opt of the TAG program must establish procedures to gather the necessary daily data beginning July 1, 2010.

As indicated previously, the dollar amounts of TAG-related accounts are sizeable, and many institutions rely significantly on these accounts as a funding source. However, the FDIC notes that these balances are often held in a relatively small number of individual accounts. The FDIC further notes that certain institutions with total assets of more than $1 billion, all de novo IDIs, and some other IDIs already report their regular deposit insurance assessment balances based on an average daily balance basis and currently have in place the systems to report their TAG-qualifying account balances on an average daily basis. All other institutions report their deposit insurance assessment base on a quarter-end basis. However, of those institutions that use quarter-end reporting, fewer than 1,000 institutions report more than 25 TAG-qualifying accounts.

Given the limited number of these accounts that would be included in an

IDI's average daily balance reporting base and the larger number of IDIs that currently use average daily balances reporting, the FDIC does not believe that this change in assessment base would create a significant administrative burden on IDIs that do not currently employ average daily balance reporting.

D. Treatment of NOW Accounts

Currently, the TAG program provides for an FDIC guarantee of NOW accounts with interest rates no higher than 0.50 percent at participating IDIs that have committed to maintain that rate for the duration of the program. At the inception of the TAG program, 0.50 percent was viewed as a low rate of interest and, as such, a NOW account paying no more than this rate would be substantially similar to a noninterest bearing transaction account. Under the November 2008 Final Rule for the TLGP, these accounts were included in the TAG program to provide stability to payment processing accounts structured as NOW accounts, without creating the risk of destabilizing money market mutual finds or allowing weaker institutions to attract deposits in these ownership categories through offering higher interest rates.

However, the prevailing nationwide average rates for regular interest-bearing checking accounts now range from 0.12 percent to 0.16 percent for most accounts, and from 0.26 percent to 0.29 percent for premium interest bearing accounts held by municipalities, school districts, and other typical large transaction account holders.[20] In order to align NOW accounts covered by the TAG program with current market rates and to ensure the program is not used inappropriately by institutions to attract interest-rate-sensitive deposits to fund risk activities, the Interim Rule reduces the interest rate on NOW accounts eligible for the FDIC's guarantee from a maximum of 0.50 percent to a maximum of 0.25 percent. The Interim Rule also requires participating IDIs to commit to maintain the interest rate at or below 0.25 percent after June 30, 2010, and through December 31, 2010, or December 31, 2011, if the Board further extends the TAG program.

The Interim Rule does not prescribe specific disclosures related to NOW accounts. Participating IDIs are reminded, however, that contractual terms governing individual deposit accounts, as well as provisions of the Truth in Savings Act,[21] may require disclosures to consumers regarding modifications of interest rates on applicable NOW accounts. Moreover, if an IDI offers both TAG-qualifying and non-qualifying NOW accounts, appropriate disclosures should be provided in order to avoid consumer confusion.

E. Opportunity To Opt Out of the Extended TAG Program

The Interim Rule imposes certain regulatory modifications to the existing TAG program. Some IDIs currently participating in the TAG may feel that their existing financial condition or future business plans would be best served by discontinuing their involvement in the TAG program. For these reasons, the Interim Rule provides IDIs currently participating in the TAG program with a one-time, irrevocable opportunity to opt out of this TAG extension. A participating IDI's decision to remain in the extended TAG program obligates it to remain in the program through December 31, 2010, or for an additional 12 months if the Board further extends the TAG program. An IDI that wishes to opt out of the TAG extension must provide the FDIC with notice of its intent to opt out by April 30, 2010 by submitting an e-mail with the subject line "TLGP Election Form Opt Out Requested—Cert No. XXXXX" to *optout@fdic.gov.* The e-mail must include the following information: name of the IDI; FDIC certificate number; city, state, and zip code for the IDI; contact name and contact information (telephone number and e-mail address); a concise statement that the IDI would like to opt out of the TAG program effective July 1, 2010; and confirmation that, no later than May 20, 2010, the IDI will post a notice in the lobby of its main office, each domestic branch, and if it offers Internet deposit services, on its website, clearly indicating that funds held in noninterest-bearing transaction accounts that are in excess of the standard maximum deposit insurance amount will not be guaranteed under the TAG program after June 30, 2010.

Once this information has been received and processed, FDIC staff will contact the IDI to confirm the IDI's opt out decision.

F. Disclosure Requirements

Current Disclosure Requirements

Regulations governing the existing TAG program contain certain disclosure requirements. Among other things, each IDI that offers noninterest-bearing transaction accounts is required to post a prominent notice in the lobby of its main office, in each domestic branch and, if it offers Internet deposit services, on its Web site clearly indicating whether the institution is participating in the TAG program.[22] If an IDI is participating in the TAG program, the notice must state that funds held in noninterest-bearing transaction accounts at the institution are guaranteed in full by the FDIC. Although existing regulations do not require specific language to appear in disclosures regarding the TAG program, the notices must be provided in simple, readily understandable text.

Disclosure Requirements for IDIs Participating in the Extended TAG Program

Under the Interim Rule, participating IDIs that do not opt out of the extended TAG program will be required to amend these disclosures on or before May 20, 2010. The Interim Rule requires IDIs that choose to remain in the TAG program to update their disclosures to reference December 31, 2010, as the termination date for this extension of the TAG program. Further disclosures may be required if the Board determines that the TAG program should be extended through December 31, 2011.

Disclosure Requirements for IDIs Opting Out of the Extended TAG Program

On or before May 20, 2010, participating IDIs that opt out of the extended TAG program will be required to update their disclosures to inform customers and depositors that, beginning on July 1, 2010, they will no longer participate in the TAG program and the deposits in noninterest-bearing transaction accounts will no longer be guaranteed in full by the FDIC.

V. Request for Comments

The FDIC requests comments on all aspects of the Interim Rule and solicits suggestions regarding its implementation, especially as to the change in reporting basis for assessment purposes.

VI. Regulatory Analysis and Procedure

A. Regulatory Flexibility Act

The process of amending part 370 by means of this Interim Rule is governed by the Administrative Procedure Act (APA). Pursuant to section 553(b)(B) of the APA, general notice and opportunity for public comment are not required with respect to a rule making when an agency for good cause finds that "notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." Similarly, section 553(d)(3) of the APA provides that the publication of a rule shall be made not less than 30 days before its effective

[20] FDIC analysis of data provided by RateWatch.

[21] 12 U.S.C. 4301, *et seq.*

[22] 12 CFR 370.5(h)(5).

date, except "* * * (3) as otherwise provided by the agency for good cause found and published with the rule."

Consistent with section 553(b)(B) of the APA, the FDIC finds that good cause exists for a finding that general notice and opportunity for public comment are impracticable and contrary to the public interest. The TLGP was announced by the FDIC on October 14, 2008, as an initiative to counter the system-wide crisis in the nation's financial sector, and involved a determination of systemic risk by the Secretary of the Treasury after consultation with the President. The systemic risk determination allowed the FDIC to take certain actions to avoid or mitigate serious adverse effects on economic conditions and financial stability. The purpose of the TLGP is to promote financial stability by preserving confidence in the banking system and facilitating the flow of liquidity to creditworthy businesses and consumers, favorably affecting both the availability and cost of credit. Immediate issuance of this Interim Rule furthers the public interest by extending the time period of the TAG program to promote continued stability in the banking system through guaranteeing large uninsured transaction account balances in order to provide participating IDIs with continued sources of funding to meet their liquidity needs. For these same reasons, the FDIC finds good cause to publish this Interim Rule with an immediate effective date.[23]

Although general notice and opportunity for public comment are not required prior to the effective date, the FDIC invites comments on all aspects of the Interim Rule, which the FDIC may revise if necessary or appropriate in light of the comments received.

B. Riegle Community Development and Regulatory Improvement Act

The Riegle Community Development and Regulatory Improvement Act provides that any new regulations or amendments to regulations prescribed by a Federal banking agency that impose additional reporting, disclosures, or other new requirements on insured depository institutions shall take effect on the first day of a calendar quarter which begins on or after the date on which the regulations are published in final form, unless the agency determines, for good cause published with the rule, that the rule should become effective before such time.[24] For the same reasons discussed above, the FDIC finds that good cause exists for an immediate effective date for the Interim Rule.

C. Small Business Regulatory Enforcement Fairness Act

The Office of Management and Budget (OMB) has yet to issue its determination as to whether the Interim Rule is a "major rule" within the meaning of the relevant sections of the Small Business Regulatory Enforcement Act of 1996 (SBREFA), 5 U.S.C. 801 *et seq.* However, a previous rule extending the TAG Program was determined by OMB to be "not major" and the FDIC believes that this Interim Rule is also "not major." As required by SBREFA, the FDIC will file the appropriate reports with Congress and the Government Accountability Office as soon as it receives a determination from OMB. Nevertheless, as discussed above, consistent with section 553(b)(B) of the APA, the FDIC has determined for good cause that general notice and opportunity for public comment would be impracticable and contrary to the public interest. Therefore, in accordance with 5 U.S.C. 808(2), this Interim Rule will take effect upon publication in the **Federal Register**.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (Pub. L. No. 96–354, Sept. 19, 1980) (RFA) applies only to rules for which an agency publishes a general notice of proposed rule making pursuant to 5 U.S.C. 553(b). As discussed above, consistent with section 553(b)(B) of the APA, the FDIC has determined for good cause that general notice and opportunity for public comment would be impracticable and contrary to the public interest. Therefore, the RFA, pursuant to 5 U.S.C. 601(2), does not apply.

E. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), 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. This Interim Rule, by extending the termination date for the TAG Program, will change the estimated number of respondents for the reporting and recordkeeping requirements in an existing OMB-approved information collection, entitled the "Transaction Account Guarantee Program Extension," (OMB No. 3064–0170). These burden adjustments are being submitted to OMB as a request for a nonmaterial/nonsubstantive change.

Currently, there are 6,340 institutions participating in the TAG program. Pursuant to sections 370.5(c)(3) and (g)(3) of the Interim Rule, institutions that do not wish to participate in the program extension must request authorization by April 30, 2010, to opt out of the TAG Program, effective July 1, 2010. The FDIC estimates that approximately one-third of current participants will elect to opt-out of the extension. In addition, section 370.5(h)(5) requires continuing program participants to update notices posted in the lobby of their main offices and domestic branches and, if applicable, on their Web sites, to reflect the new TAG expiration date. The FDIC estimates that approximately two-thirds of current participants will be required to update their disclosures to reflect a new termination date for the TAG program. In the event the FDIC exercises the option to extend the program for an additional 12 months without further rulemaking, it estimates that the same number of participants may need to update their disclosures a second time. Any further adjustments to burden estimates required by a decision to extend the program for an additional 12 months will be submitted to OMB at the time the extension is announced.

Although Section 370.7(c)(5) requires that a new data element on average daily balances in noninterest-bearing transaction accounts be incorporated into the Consolidated Report of Income and Condition (CALL Report) filed by program extension participants, the reporting requirement will not be implemented until the quarterly report filed for the period July 1, 2010, to September 30, 2010. This change to the CALL Report will be the subject of a separate notice under the Paperwork Reduction Act.

Therefore, the new estimated burden for the Transaction Account Guarantee Program Extension information collection is as follows:

Title: Temporary Transaction Account Guarantee Program Extension.

OMB Number: 3064–0166.

Affected Public: Insured depository institutions.

Estimated Number of Respondents:

Opt out of TAG program extension/disclosure—2,113.

Updated Disclosures by Participants to Amend Termination Date—4,227.

Frequency of Response:

Opt out of TAG program extension/disclosure—once.

Updated Disclosures by Participants to Amend Termination Date—once.

Average Time per Response:

Opt out of TAG program extension/disclosure—1 hour.

Updated Disclosures by Participants to Amend Termination Date—1 hour.

[23] 5 U.S.C. 553(d)(3).

[24] 12 U.S.C. 4802.

Estimated New Annual Burden:

Opt out of TAG program extension/disclosure—2,113 hours.

Updated Disclosures by Participants to Amend Termination Date—4227 hours.

Current Annual Burden—7,109 hours.

Total New Burden—6,340 hours.

Total Adjusted Annual Burden—13,449 hours.

The FDIC has a continuing interest in public feedback on its information collections and paperwork burden estimates. Accordingly, public comment is invited on: (1) Whether this collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (2) the accuracy of the estimates of the burden of the information collection, including the validity of the methodologies 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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology. Interested parties are invited to submit written comments on the estimated burden for information collections associated with the TAG program extension by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federalpropose.html.*
- *E-mail: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Leneta Gregorie (202–898–3719), Counsel, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 550 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

A copy of the comment may also be submitted to the OMB Desk Officer for the FDIC, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503. All comments should refer to the name and number of the collection.

F. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106–102, 113 Stat. 1338, 1471 (Nov. 12, 1999), requires the federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The FDIC invites your comments on how to make this regulation easier to understand. For example:

- Has the FDIC organized the material to suit your needs? If not, how could this material be better organized?
- Are the requirements in the regulation clearly stated? If not, how could the regulation be more clearly stated?
- Does the regulation contain language or jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes to the format would make the regulation easier to understand?
- What else could the FDIC do to make the regulation easier to understand?

G. The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The FDIC has determined that the interim rule will not affect family well-being within the measure of section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681).

List of Subjects in 12 CFR Part 370

Banks, Banking, Bank deposit insurance, Holding companies, National banks, Reporting and recordkeeping requirements, Savings associations.

■ For the reasons discussed in the preamble, the Federal Deposit Insurance Corporation amends part 370 of chapter III of Title 12 of the Code of Federal Regulations as follows:

PART 370—TEMPORARY LIQUIDITY GUARANTEE PROGRAM

■ 1. The authority citation for part 370 continues to read as follows:

Authority: 12 U.S.C. 1813(l), 1813(m), 1817(i), 1818, 1819(a)(Tenth), 1820(f), 1821(a), 1821(c), 1821(d), 1823(c)(4).

■ 2. Amend § 370.2 as follows:

■ a. Revise paragraph (g),

■ b. Revise paragraphs (h)(3) and (h)(4), and

■ c. Add paragraph (o), to read as follows:

§ 370.2 Definitions.

* * * * *

(g) *Participating entity.* (1) Except as provided in paragraphs (g)(2) and (g)(3) of this section, the term "participating entity" means with respect to each of the debt guarantee program and the transaction account guarantee program,

(i) An eligible entity that became an eligible entity on or before December 5, 2008 and that has not opted out, or

(ii) An entity that becomes an eligible entity after December 5, 2008, and that the FDIC has allowed to participate in the program, except.

(2) A participating entity that opted out of the transaction account guarantee program in accordance with § 370.5(c)(2) ceased to be a participating entity in the transaction account guarantee program effective on January 1, 2010.

(3) A participating entity that opts out of the transaction account guarantee program in accordance with § 370.5(c)(23) ceases to be a participating entity in the transaction account guarantee program effective on July 1, 2010.

* * * * *

(h) * * *

(3) Notwithstanding paragraphs (h)(1) and (h)(2) of this section, for purposes of the transaction account guarantee program, a noninterest-bearing transaction account includes:

(i) Accounts commonly known as Interest on Lawyers Trust Accounts (IOLTAs) (or functionally equivalent accounts); and

(ii) Negotiable order of withdrawal accounts (NOW accounts) with interest rates:

(A) No higher than 0.50 percent through June 30, 2010, if the insured depository institution at which the account is held has committed to maintain the interest rate at or below 0.50 percent. through June 30, 2010; and

(B) No higher than 0.25 percent after June 30, 2010, if the insured depository institution at which the account is held has committed to maintain the interest rate at or below 0.25 percent after June 30, 2010 through the TAG expiration date.

(4) Notwithstanding paragraph (h)(3) of this section, a NOW account with an interest rate above 0.50 percent as of November 21, 2008, may be treated as a noninterest-bearing transaction account for purposes of this part:

(i) Through June 30, 2010, if the insured depository institution at which the account is held reduced the interest rate on that account to 0.50 percent or lower before January 1, 2009, and committed to maintain that interest rate at no more than 0.50 percent through June 30, 2010; and

(ii) After June 30, 2010 through the TAG expiration date, if the insured depository institution at which the account is held reduces the interest rate

on that account to 0.25 percent or lower before July 1, 2010, and commits to maintain that interest rate at no more than 0.25 percent through the TAG expiration date.

* * * * *

(o) *TAG expiration date.* The term "TAG expiration date" means December 31, 2010 unless the Board of Directors of the FDIC (the "Board"), for good cause, extends the transaction account guarantee program for an additional year in which case the term "TAG expiration date" means December 31, 2011. Good cause exists if the Board finds that the economic conditions and circumstances that led to the establishment of the transaction account guarantee program are likely to continue beyond December 31, 2010 and that extending the transaction account guarantee program for an additional year will help mitigate or resolve those conditions and circumstances. If the Board decides to extend the transaction account guarantee program to December 31, 2011, it will do so without further rulemaking; however, the FDIC will publish notice of any extension no later than October 29, 2010.

■ 3. Amend § 370.4 by revising paragraph (a) to read as follows:

§ 370.4 Transaction Account Guarantee Program.

(a) In addition to the coverage afforded to depositors under 12 CFR Part 330, a depositor's funds in a noninterest-bearing transaction account maintained at a participating entity that is an insured depository institution are guaranteed in full (irrespective of the standard maximum deposit insurance amount defined in 12 CFR 330.1(n)) from October 14, 2008 through:

(1) The date of opt-out, in the case of an entity that opted out prior to December 5, 2008;

(2) December 31, 2009, in the case of an entity that opted out effective on January 1, 2010; or

(3) June 30, 2010, in the case of an entity that opts out of the transaction account guarantee program effective on July 1, 2010; or

(4) The TAG expiration date, in the case of an entity that does not opt out.

* * * * *

■ 4. Amend § 370.5 as follows:

■ a. Add paragraph (c)(3),

■ b. Revise paragraph (g)(1),

■ c. Add paragraph (g)(3), and

■ d. Revise paragraph (h)(5), to read as follows:

§ 370.5 Participation.

* * * * *

(c) * * *

(3) Any insured depository institution that is participating in the transaction account guarantee program may request authorization to opt out of such program effective on July 1, 2010. Any such election to opt-out must be made in accordance with the procedures set forth in paragraph (g)(3) of this section. If the FDIC grants the request, the opt out is irrevocable.

* * * * *

(g) * * *

(1) Except as provided in paragraphs (g)(2) and (g)(3) of this section, the FDIC will provide procedures for opting out and for making an affirmative decision to opt in using FDIC's secure e-business Web site, FDICconnect. Entities that are not insured depository institutions will select and solely use an affiliated insured depository institution to submit their opt-out election or their affirmative decision to opt in.

* * * * *

(3) Pursuant to paragraph (c)(3) of this section a participating entity may request authorization to opt out of the transaction account guarantee program effective on July 1, 2010 by submitting to the FDIC on or before 11:59 p.m., Eastern Daylight Saving Time, on April 30, 2010 an e-mail conveying the entity's request to opt out. The subject line of the e-mail must include: "TLGP Request to Opt Out—Cert. No. _____." The e-mail must be addressed to *optout@fdic.gov* and must include the following:

(i) Institution Name;

(ii) FDIC Certificate number;

(iii) City, State, ZIP;

(iv) Name, Telephone Number and Email Address of a Contact Person;

(v) A statement that the institution is requesting authorization to opt out of the transaction account guarantee program effective July 1, 2010; and

(vi) Confirmation that no later than May 20, 2010 the institution will post a prominent notice in the lobby of its main office and each domestic branch and, if it offers Internet deposit services, on its Web site clearly indicating that after June 30, 2010, funds held in noninterest-bearing transaction accounts will no longer be guaranteed in full under the Transaction Account Guarantee Program, but will be insured up to $250,000 under the FDIC's general deposit insurance rules.

* * * * *

(h) * * *

(5) Each insured depository institution that offers noninterest-bearing transaction accounts must post a prominent notice in the lobby of its main office, each domestic branch and, if it offers Internet deposit services, on its Web site clearly indicating whether the institution is participating in the transaction account guarantee program. If the institution is participating in the transaction account guarantee program, the notice must state that funds held in noninterest-bearing transactions accounts at the entity are guaranteed in full by the FDIC. Participating entities must update their disclosures to reflect the current TAG expiration date, including any extension pursuant to § 370.2(o) or, if applicable, any decision to opt-out.

(i) These disclosures must be provided in simple, readily understandable text. Sample disclosures are as follows:

For Participating Institutions

[Institution Name] is participating in the FDIC's Transaction Account Guarantee Program. Under that program, through [June 30, 2010, December 31, 2010, or December 31, 2011, whichever is applicable], all noninterest-bearing transaction accounts are fully guaranteed by the FDIC for the entire amount in the account.

Coverage under the Transaction Account Guarantee Program is in addition to and separate from the coverage available under the FDIC's general deposit insurance rules.

For Participating Institutions That Elect to Opt-out of the Extended Transaction Account Guaranty Program Effective on July 1, 2010

Beginning July 1, 2010 [Institution Name] will no longer participate in the FDIC's Transaction Account Guarantee Program. Thus, after June 30, 2010, funds held in noninterest-bearing transaction accounts will no longer be guaranteed in full under the Transaction Account Guarantee Program, but will be insured up to $250,000 under the FDIC's general deposit insurance rules.

For Non-Participating Institutions

[Institution Name] has chosen not *to participate in the FDIC's Transaction Account Guarantee Program. Customers of [Institution Name] with noninterest-bearing transaction accounts will continue to be insured for up to $250,000 under the FDIC's general deposit insurance rules.*

(ii) If the institution uses sweep arrangements or takes other actions that result in funds being transferred or reclassified to an account that is not guaranteed under the transaction account guarantee program, for example, an interest-bearing account, the institution must disclose those

actions to the affected customers and clearly advise them, in writing, that such actions will void the FDIC's guarantee with respect to the swept, transferred, or reclassified funds.

* * * * *

■ 5. Amend § 370.7 by revising paragraphs (b) and (c) to read as follows:

§ 370.7 Assessment for the Transaction Account Guarantee program.

* * * * *

(b) *Initiation of assessments.* Beginning on November 13, 2008 each eligible entity that does not opt out of the transaction account guarantee program on or before December 5, 2008 will be required to pay the FDIC assessments on all deposit amounts in noninterest-bearing transaction accounts calculated in accordance with paragraph (c) of this section.

(c) *Amount of assessment.*

(1) Except as provided in paragraphs (c)(2) and (c)(3) of this section any eligible entity that does not opt out of the transaction account guarantee program shall pay quarterly an annualized 10 basis point assessment on any deposit amounts exceeding the existing deposit insurance limit of $250,000, as reported on its quarterly Consolidated Reports of Condition and Income, Thrift Financial Report, or Report of Assets and Liabilities of U.S. Branches and Agencies of Foreign Banks (each, a "Call Report") in any noninterest-bearing transaction accounts (as defined in § 370.2(h)), including any such amounts swept from a noninterest-bearing transaction account into an noninterest-bearing savings deposit account as provided in § 370.4(c).

(2) For the period after December 31, 2009 through and including June 30, 2010, each participating entity that does not opt out of the transaction account guarantee program in accordance with § 370.5(c)(2) shall pay quarterly a fee based upon its Risk Category rating. The amount of the fee for each such entity is equal to the annualized, TAG assessment rate for the entity multiplied by the amount of the deposits held in noninterest-bearing transaction accounts (as defined in § 370.2(h) and including any amounts swept from a noninterest-bearing transaction account into an noninterest-bearing savings deposit account as provided in § 370.4(c)) that exceed the existing deposit insurance limit of $250,000, as reported on the entity's most recent quarterly Call Report.

(3) Beginning on July 1, 2010, each participating entity that does not opt out of the transaction account guarantee program shall pay quarterly a fee based upon its Risk Category rating. The amount of the fee for each such entity is equal to the annualized, TAG assessment rate for the entity multiplied by the aggregate amount of the deposits held in noninterest-bearing transaction accounts (as defined in § 370.2(h) and including any amounts swept from a noninterest-bearing transaction account into an noninterest-bearing savings deposit account as provided in § 370.4(c)) that exceed the existing deposit insurance limit of $250,000, calculated based upon the average daily balances in such accounts as reported on the entity's most recent quarterly Call Report.

(4) The annualized TAG assessment rates are as follows:

(i) 15 basis points, for the portion of each quarter in which the entity is assigned to Risk Category I;

(ii) 20 basis points, for the portion of each quarter in which the entity is assigned to Risk Category II; and

(iii) 25 basis points, for the portion of each quarter in which the entity is assigned to either Risk Category III or Risk Category IV.

(5) The amount to be reported for each noninterest-bearing transaction account as the average daily balance is the total dollar amount held in such account that exceeds $250,000 for each calendar day during the quarter divided by the number of calendar days in the quarter. For those days that an office of the reporting institution is closed (*e.g.,* Saturdays, Sundays, or holidays), the amounts outstanding from the previous business day should be used. The total number of accounts to be reported should be calculated on the same basis. Documentation supporting the amounts used in the calculation of the average daily balance amounts must be retained and be readily available upon request by the FDIC or the institution's primary Federal regulator. In addition, all institutions that do not opt of the transaction account guarantee program must establish procedures to gather the necessary daily data beginning July 1, 2010.

(6) An entity's Risk Category is determined in accordance with the FDIC's risk-based premium system described in 12 CFR part 327. The assessments provided in this paragraph (c) shall be in addition to an institution's risk-based assessment imposed under Part 327.

* * * * *

By order of the Board of Directors.

Dated at Washington, DC, this 13th day of April, 2010.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2010–8911 Filed 4–16–10; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0329; Directorate Identifier 2009–CE–020–AD; Amendment 39–16264; AD 2009–08–05 R1]

RIN 2120–AA64

Airworthiness Directives; Liberty Aerospace Incorporated Model XL–2 Airplanes

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

ACTION: Final rule.

SUMMARY: We are correcting the address, telephone, and fax information for the reporting requirement in Airworthiness Directive (AD) 2009–08–05, which applies to certain Liberty Aerospace Incorporated Model XL–2 airplanes. AD 2009–08–05 currently requires repetitively inspecting the exhaust muffler for cracks, replacing the exhaust muffler when cracks are found, and reporting the results of the inspections to the FAA. Since AD 2009–08–05 became effective, the FAA's Atlanta Aircraft Certification Office (ACO) moved, which has caused the office personnel problems in receiving fax and mailed copies of the inspection result reports. This document corrects the mailing address, telephone number, and fax information of the Atlanta ACO.

DATES: This final rule is effective April 19, 2010. The compliance date of this AD is April 20, 2009, which is the same as the effective date of AD 2009–08–05.

As of April 20, 2009 (74 FR 16117, April 9, 2009), the Director of the Federal Register approved the incorporation by reference of Liberty Aerospace, Inc. Service Document Critical Service Bulletin (CSB) CSB–09–001, Revision Level B, Revised on March 18, 2009.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at 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:

—Corey Spiegel, Aerospace Engineer, Atlanta Aircraft Certification Office, 1701 Columbia Avenue, College Park, Georgia 30337; *telephone:* (404) 474–5574; *facsimile:* (404) 474–5606; *e-mail: corey.spiegel@faa.gov;* or
—Cindy Lorenzen, Aerospace Engineer, Atlanta Aircraft Certification Office, 1701 Columbia Avenue, College Park, Georgia 30337; *telephone:* (404) 474–5524; *facsimile:* (404) 474–5606; *e-mail: cindy.lorenzen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On April 3, 2009, we issued AD 2009–08–05, Amendment 39–15878 (74 FR 16117, April 9, 2009), to require repetitively inspecting the exhaust muffler for cracks, replacing the exhaust muffler when cracks are found, and reporting the results of the inspections to the FAA.

Since AD 2009–08–05 became effective, the FAA's Atlanta Aircraft Certification Office (ACO) moved, which has caused the office personnel problems in receiving fax and mailed copies of the inspection result reports.

Consequently, the FAA sees a need to correct the mailing address, telephone number, and fax information of the Atlanta ACO in AD 2009–08–05 to assure that the inspection results are received and reviewed to help assure the continued operational safety of the affected airplanes. Thus, the FAA is revising the AD to incorporate the language discussed above and to add the amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13).

Since this action only corrects the address, telephone number, and fax information for the reporting requirement and does not require any additional actions over that originally required by AD 2009–08–05, it has no adverse economic impact and imposes no additional burden on any person than was already required. Therefore, the FAA has determined that prior notice and opportunity for public comment are unnecessary.

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 removing Airworthiness Directive (AD) 2009–08–05, Amendment 39–15878 (74 FR 16117, April 9, 2009), and adding the following new AD:

2009–08–05 R1 Liberty Aerospace Incorporated: Amendment 39–16264; Docket No. FAA–2009–0329; Directorate Identifier 2009–CE–020–AD.

Effective Date

(a) This final rule is effective April 19, 2010. The compliance date of this AD is April 20, 2009, which is the same as the effective date of AD 2009–08–05.

Affected ADs

(b) This AD revises AD 2009–08–05.

Applicability

(c) This AD applies to Model XL–2 airplanes, serial numbers 0007, 0009, and subsequent, that are certificated in any category.

Unsafe Condition

(d) This AD is the result of reports that eight cracks have been found in the exhaust muffler during maintenance and service inspections. We are issuing this AD to detect and correct cracks in the exhaust muffler, which could result in carbon monoxide entering the cabin heating system. This condition could lead to incapacitation of the pilot.

Compliance

(e) To address this problem, you must do the following, unless already done:

Actions	Compliance	Procedures
(1) Inspect the following: (i) The exhaust muffler for cracks. There are two different exhaust systems available for the affected airplanes. They are: (A) Standard exhaust system, part number (P/N) DEL200201–002 that incorporates muffler P/N DEL200201–101; and (B) Reduced sound exhaust system, P/N DEL200201–003 that incorporates muffler P/N 200201–104. (ii) The tail pipe and the tail pipe opening in the lower cowl for a 0.5-inch minimum clearance. (iii) Inspect the propeller for proper propeller clocking position.	Initially inspect within the next 10 hours time-in-service (TIS) after April 20, 2009 (the effective date of AD 2009–08–05) or at the next annual inspection, whichever occurs first. Repetitively inspect the exhaust muffler thereafter as specified in paragraph (e)(5) of this AD.	Follow Liberty Aerospace, Inc. Service Document Critical Service Bulletin (CSB) CSB–09–001, Revision Level B, Revised on March 18, 2009.
(2) As a result of the inspections required in paragraphs (e)(1)(ii) and (e)(1)(iii) of this AD: (i) If the clearance between the tail pipe and the tail pipe opening is less than the required 0.5-inch minimum, trim the lower cowl as needed to achieve the minimum clearance. (ii) If there is a discrepancy in the propeller clocking position, remove and reinstall the propeller at the correct position.	Before further flight after the inspection required in paragraph (e)(1) of this AD.	As specified in Liberty Aerospace, Inc. Service Document Critical Service Bulletin (CSB) CSB–09–001, Revision Level B, Revised on March 18, 2009.

Actions	Compliance	Procedures
(3) As a result of the initial inspection required in paragraph (e)(1)(i) of this AD or any repetitive inspection required in paragraph (e)(5) of this AD, if a crack is found, replace the exhaust muffler. (i) The manufacturer will provide the replacement exhaust system. (ii) A reduced sound exhaust system may be replaced with a standard exhaust system. (iii) Installing a reduced sound exhaust system as a replacement part also requires installing a bypass SCAT tube and a "Do Not Use" placard on or near the heater knob.	Before further flight after the initial inspection required in paragraph (e)(1) of this AD and before further flight after any repetitive inspection required in paragraph (e)(5) of this AD.	Follow Liberty Aerospace, Inc. Service Document Critical Service Bulletin (CSB) CSB–09–001, Revision Level B, Revised on March 18, 2009.
(4) If the airplane is equipped with a reduced sound exhaust system and no cracks are found during the initial inspection required in paragraph (e)(1) of this AD, install a bypass SCAT tube and a "Do Not Use" placard on or near the heater knob.	Within the next 10 hours TIS after April 20, 2009 (the effective date of AD 2009–08–05).	Follow Liberty Aerospace, Inc. Service Document Critical Service Bulletin (CSB) CSB–09–001, Revision Level B, Revised on March 18, 2009.
(5) If no cracks are found in the exhaust muffler during the initial inspection required in paragraph (e)(1) of this AD or if the exhaust muffler was replaced as required in paragraph (e)(3) of this AD, repetitively inspect thereafter at the intervals specified in paragraphs (e)(5)(i), (e)(5)(ii), and (e)(5)(iii) of this AD.	(i) For airplanes equipped with a standard exhaust system and the optional bypass SCAT tube has not been installed, repetitively inspect thereafter every 25 hours TIS or every 12 months, whichever occurs first. (ii) For airplanes equipped with a standard exhaust system and the optional bypass SCAT tube has been installed, repetitively inspect thereafter every 50 hours TIS or every 12 months, whichever occurs first. (iii) For airplanes equipped with a reduced sound exhaust system and the required bypass SCAT tube has been installed, repetitively inspect thereafter every 50 hours TIS or every 12 months, whichever occurs first.	Follow Liberty Aerospace, Inc. Service Document Critical Service Bulletin (CSB) CSB–09–001, Revision Level B, Revised on March 18, 2009.
(6) Report the results of the following inspections required in this AD to the FAA. (i) Initial inspection required in paragraph (e)(1) of this AD. (ii) Repetitive inspections required in paragraph (e)(5) of this AD only if cracks are found. (iii) The Office of Management and Budget (OMB) approved the information collection requirements contained in this regulation under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and assigned OMB Control Number 2120–0056.	Within 10 days after each inspection required by this AD.	Use the form (Figure 1 of this AD) and submit it to FAA, Atlanta Aircraft Certification Office, 1701 Columbia Avenue, College Park, Georgia 30337; fax: (404) 474–5606; e-mail *corey.spiegel@faa.gov.*

AD 2009–08–05 R1 Inspection Report		
Airplane Serial Number		
Airplane Tach Hours at time of inspection		
Propeller type (circle one)	MT	Sensenich
Propeller Tach Hours at time of inspection		
Exhaust Type (circle one)	Standard	Reduced Sound
Is Exhaust Cracked? (circle one)	YES	NO
Did lower cowl require trimming at the tail pipe opening? (circle one) *Not applicable after initial inspection*	YES	NO
Did the propeller clocking position need to be corrected? (circle one) *Not applicable after initial inspection.*	YES	NO
Were any other discrepancies noticed during the inspection?		
Name:		
Telephone and/or e-mail address:		
Date:		
Send report to: Corey Spiegel, Aerospace Engineer, Atlanta ACO, 1701 Columbia Avenue, College Park, Georgia 30337; *facsimile:* (404) 474–5606; *e-mail: corey.spiegel@faa.gov.*		

Figure 1

Special Flight Permit

(f) Under 14 CFR part 39.23, we are limiting the special flight permits for this AD by the following conditions:

(1) The cabin heat turned off; and

(2) The fresh air vents are open.

Alternative Methods of Compliance (AMOCs)

(g) The Manager, Atlanta Aircraft Certification Office (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:* Corey Spiegel, Aerospace Engineer, Atlanta ACO, 1701 Columbia Avenue, College Park, Georgia 30337. 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 Liberty Aerospace, Inc. Service Document Critical Service Bulletin (CSB) CSB–09–001, Revision Level B, Revised on March 18, 2009, to do the actions required by this AD, unless the AD specifies otherwise.

(1) On April 20, 2009 (74 FR 16117, April 9, 2009), the Director of the Federal Register previously 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 Liberty Aerospace, 100 Aerospace Drive, Melbourne, Florida 32901; *telephone:* (321) 752–0332 or (800) 759–5953; *fax:* (321) 752–0377; *Internet: http://www.libertyaircraft.com.*

(3) You may review copies of the service information incorporated by reference for this AD at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the Central Region, call (816) 329–3768.

(4) You may also review copies of the service information incorporated by reference for this AD 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 Kansas City, Missouri, on April 7, 2010.

Kim Smith,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010–8596 Filed 4–16–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2010–N–0002]

Implantation or Injectable Dosage Form New Animal Drugs; Change of Sponsor; Propofol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Intervet, Inc., to Teva Animal Health, Inc.

DATES: This rule is effective April 19, 2010.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: *david.newkirk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, has informed FDA that it has transferred ownership of, and all rights and interest in, approved NADA 141–070 for RAPINOVET (propofol), an

injectable anesthetic, to Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503. Accordingly, the agency is amending the regulations in 21 CFR 522.2005 to reflect the transfer of ownership and a current format.

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

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Revise § 522.2005 to read as follows:

§ 522.2005 Propofol.

(a) *Specifications.* Each milliliter of emulsion contains 10 milligrams (mg) propofol.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 059130 for use as in paragraph (c) of this section.

(2) No. 000074 for use as in paragraphs (c)(1)(i), (c)(2), and (c)(3) of this section.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* The drug is administered by intravenous injection as follows:

(i) *Dogs.* For induction of general anesthesia without the use of preanesthetics the dosage is 5.5 to 7.0 mg per kilogram (mg/kg) (2.5 to 3.2 mg/pound (lb)); for the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 3.3 mg/kg (0.5 to 1.5 mg/lb). The use of preanesthetic medication reduces propofol dose requirements.

(ii) *Cats.* For induction of general anesthesia without the use of preanesthetics the dosage is 8.0 to 13.2 mg/kg (3.6 to 6.0 mg/lb). For the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 4.4 mg/kg (0.5 to 2.0 mg/lb). The use of preanesthetic medication reduces propofol dose requirements.

(2) *Indications for use.* As a single injection to provide general anesthesia for short procedures; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 13, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010–8945 Filed 4–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 1003

[Docket No. FR–5232–F–02]

RIN 2577–AC79

Regulatory Reporting Requirements for the Indian Community Development Block Grant Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Final rule.

SUMMARY: This final rule revises the reporting requirements for the Indian Community Development Block Grants (ICDBG) program. First, the rule provides for submission of a single annual report on the hiring of minority business enterprises, due each October. Currently, ICDBG grantees are required to report on these activities on a semiannual basis, with reports being due to HUD on April 10 and October 10 of each year. Second, this rule requires ICDBG grantees to use the Logic Model form developed as part of HUD's Notice of Funding Availability (NOFA) process. The required use of the Logic Model will conform the ICDBG reporting requirements to those of other HUD competitive funding programs, and enhance the evaluation of grantee performance by ensuring uniformity in the information provided by ICDBG grantees on performance goals. This final rule follows publication of an October 23, 2009, proposed rule on which HUD received two public comments, both of which were supportive of the rule.

DATES: *Effective Date:* May 19, 2010.

FOR FURTHER INFORMATION CONTACT: Deborah Lalancette, Director, Office of Grants Management, Office of Native American Programs, Department of Housing and Urban Development, 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 at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

On October 23, 2009 (74 FR 54886), HUD published for public comment a proposed rule to revise the reporting requirements for the Indian Community Development Block Grant (ICDBG) program. 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.

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"). Section 1003.506 of the ICDBG program regulations establishes several reporting requirements for ICDBG grantees. Specifically, grantees are required to submit an annual status and evaluation report (ASER) on previously funded open grants 45 days after the end of the fiscal year (FY) and upon grant closeout (§ 1003.506(a)). ICDBG grantees are also required to report on minority-owned business enterprises on a semiannual basis, with reports being due to HUD on April 10 and October 10 of each year (§ 1003.506(b)). HUD requires submission of these semiannual reports to evaluate ICDBG grantee compliance with the government-wide grant requirements regarding contracting with minority-owned business enterprises codified at 24 CFR 85.36(e). HUD believes that a single report would be less burdensome for grantees to prepare and would be enough for HUD to monitor compliance with the part 85 minority business enterprise requirements. Therefore, this final rule, consistent with the October 23, 2009, proposed rule, revises § 1003.506(b) to provide for a single annual report to be due each October 10.

Each year, HUD publishes NOFAs that announce funding availability for the majority of HUD's competitive grant programs, including the ICDBG program. The FY 2004 NOFA process introduced a planning form known as the Logic Model (form HUD–96010). Most grantees are required to submit a Logic Model form that identifies the problem or need the grant will address,

the services or activities to be provided with grant funding, and the reporting tools that will be used to measure results achieved. Indian tribes have not been required to use the Logic Model form. Nevertheless, several ICDBG grantees have chosen to use the Logic Model.

This exemption for Indian tribes was based on HUD's desire to consult with Indian tribes before making the form HUD–96010 a mandatory reporting requirement for ICDBG grant funding. As more fully described in section III of the preamble to the October 23, 2009, proposed rule, HUD consulted with Indian tribes on the Logic Model form. After considering the views and opinions expressed during the consultation process, HUD announced its intent, through publication of the October 23, 2009, proposed rule, to require use of the Logic Model as an ICDBG program requirement.

The proposed rule continued HUD's process of developing the regulatory changes with active tribal participation, by soliciting comments from the public on the mandatory use of the Logic Model in the ICDBG program. As noted, several Indian tribes already use form HUD–96010. The use of the Logic Model form, as required by this final rule, will help ensure uniformity in the information provided by ICDBG grantees on performance goals, and thereby facilitate the evaluation of grantee performance. The Logic Model will be included as part of the ASER requirement, which is codified at § 1003.506(a).

II. This Final Rule; Discussion of Public Comments Received on the October 23, 2009, Proposed Rule

This final rule follows publication of the October 23, 2009, proposed rule and takes into consideration the public comments received on the proposed rule. After considering the comments, HUD has decided to adopt the October 23, 2009, proposed rule without change.

The public comment period on the proposed rule closed on December 22, 2009, and HUD received two comments from an Indian tribal community development agency and an individual citizen. Both commenters expressed support for the proposed rule. One commenter stated that the new requirement to provide HUD a single annual report on the hiring of minority business enterprises will reduce redundant paperwork and eliminate duplicative reporting. The second commenter stated support for HUD's effort to conform the ICDBG reporting requirements with those of other HUD funding programs in order to ensure the uniformity of information provided by grantees on performance goals.

III. Findings and Certifications

Paperwork Reduction Act

The information collection requirements contained in this final 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) and assigned OMB Control Number 2535–0114. 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.

Regulatory Flexibility Act

The Regulatory Flexibility Act (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 final rule would not impose any economic burdens on small entities. Rather, the regulatory amendments will simplify and reduce the reporting requirements for ICDBG program grantees. As discussed above in this preamble, the final rule will reduce the number of required small business enterprise reports from two to a single report to be submitted each October. The final rule will also require the use of the Logic Model form in the preparation of the ASER, which ICDBG grantees are already required by regulation to submit to HUD. As noted, several grantees are already using the Logic Model, which has been a familiar part of the NOFA process since FY 2004. While the format of the Logic Model is relatively new, the data collection responsibility is not. The data required is already recorded by the tribes; it will merely be presented in a new format. The required use of the Logic Model will conform the ICDBG reporting requirements to those of other HUD competitive funding programs. The change will also help ensure uniformity in the information provided by ICDBG grantees on performance goals, and thereby facilitate the evaluation of grantee performance.

For the above reasons, the undersigned has determined that the final rule will not have a significant economic impact on a substantial number of small entities.

Environmental Impact

This final 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 rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

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 Executive Order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments nor preempt state law within the meaning of the Executive 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 on the private sector. This final rule does not impose any federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of UMRA.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance 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.

■ For the reasons stated in the preamble, HUD amends 24 CFR part 1003 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 *et seq.*

■ 2. In § 1003.506, redesignate paragraph (a)(3) as paragraph (a)(4), add a new paragraph (a)(3) and revise paragraph (b) to read as follows:

§ 1003.506 Reports.

(a) * * *

(3) *Program performance.* Data on program outputs and outcomes, in a form prescribed by HUD.

* * * * *

(b) *Minority business enterprise reports.* Grantees shall submit to HUD, by October 10, a report on contract and subcontract activity during the fiscal year.

* * * * *

Dated: April 6, 2010.

Sandra Henriquez,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 2010–8924 Filed 4–16–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

[MMS–2008–OMM–0034]

RIN 1010–AD12

Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Oil and Gas Production Requirements

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: The MMS is amending the regulations regarding oil and natural gas production requirements. This is a complete rewrite of these regulations, addressing issues such as production rates, burning oil, and venting and flaring natural gas, to ensure appropriate development of these natural resources. The final rule eliminates most restrictions on production rates and clarifies limits on the amount of natural gas that can be flared or vented. The final rule is written using plain language, so it is easier to read and understand.

DATES: *Effective Date:* This rule is effective on May 19, 2010.

FOR FURTHER INFORMATION CONTACT: Amy C. White, Regulations and Standards Branch, 703–787–1665.

SUPPLEMENTARY INFORMATION:

Background

Notice of Proposed Rulemaking

On March 6, 2007, the MMS published a Notice of Proposed Rulemaking (NPR) in the **Federal Register** (72 FR 9884). This NPR requested comments on proposed revisions to 30 CFR part 250, subpart K, Oil and Gas Production Rates. The MMS accepted comments on the NPR until June 4, 2007 (90 days). We received eight comments on the NPR. These comments came from producers of oil and natural gas in the Outer Continental Shelf (OCS) and from the State of Alaska. The MMS made revisions to the proposed rule based on these comments.

Mandate of the Outer Continental Shelf Lands Act

Under the OCS Lands Act (OCSLA), MMS has the responsibility to issue regulations governing oil and natural gas production operations on the OCS. Our regulations related to oil and natural gas operations are primarily based on three responsibilities given to the MMS by the OCSLA, these include:

1. Safety;
2. Protection of the environment; and
3. Conservation of resources.

The primary purpose of the final rule is to establish criteria for oil and natural gas production to ensure conservation of resources. These regulations help ensure that the American people received the maximum benefit from oil and natural gas production by maximizing the amount of oil and natural gas that is produced and marketed. For example, these regulations establish the criteria for natural gas flaring and venting and set limits on the time that natural gas may be flared or vented. These regulations are designed to work with other MMS regulations related to safety and protection of the environment and our other responsibilities under other Federal laws.

The MMS regulates air quality under the authority of the Clear Air Act (CAA), for areas in the Gulf of Mexico located west of 87.5° longitude (western Gulf of Mexico) and the Environmental Protection Agency (EPA) has authority for air quality elsewhere on the OCS. The MMS must coordinate with EPA to implement the CAA requirements. The EPA is responsible for setting National Ambient Air Quality Standards (NAAQS); MMS enforces those standards for oil and natural gas operations on the OCS. Our air quality requirements are located at 30 CFR subpart C—Pollution Prevention and Control. In addition to the Subpart C regulations, oil and gas operators must submit projected air emissions for their entire project as part of their Development and Production Plan (DPP) or their Development Operations Coordination Document (DOCD) at 30 CFR 250.249. Requests to flare or vent natural gas must not exceed the volume approved by MMS in the DPP or DOCD.

The MMS also reviews the flaring and venting requests to determine if they trigger an air quality review under 30 CFR subpart C. However, the flaring and venting limits set in these final regulations are low enough that additional air quality review is seldom required.

With regards to greenhouse gas emissions, MMS recognizes that this is an important issue. The CAA requires MMS to coordinate our air quality regulations with EPA. If EPA establishes a NAAQS for greenhouse gas emissions, MMS would be responsible for enforcing those standards in the western Gulf of Mexico and we would develop regulations to implement that authority under the regulations at 30 CFR subpart C, as appropriate.

Purpose of These Revisions

The MMS is revising subpart K to:

(1) Update the structure and readability of the rule, bringing it into compliance with the Department of the Interior (DOI) plain language guidance;

(2) Eliminate unnecessary requirements;

(3) Clarify limits on the amount of natural gas that may be flared or vented during certain situations;

(4) Improve collection of data on flaring and venting; and

(5) Incorporate several existing Notices to Lessees (NTLs).

The DOI requires agencies to write regulations in plain language, that is in a style that will ensure the regulations are easy to read and clear. The MMS follows DOI's plain language guidelines when creating new regulations or updating existing regulations. These regulations were originally written before plain language standards were required; we are updating the entire subpart to comply with those standards.

Some requirements from the current subpart K regulations are eliminated by the final rule because they are unnecessary in today's petroleum industry. For example, MMS required operators to establish maximum production rates (MPRs) for producing well completions, and maximum efficient rates (MERs) for producing reservoirs, in OCS Order No. 11 in 1974,

during a period of oil shortages and energy crises. In 1988, MMS reduced the MER requirement. Currently, MERs are required only on sensitive reservoirs (primarily oil reservoirs with associated gas caps). Determining and maintaining production rates imposes a significant burden on operators. Based on the past 30 years of experience, MMS concluded that maximum rate requirements and production balancing requirements can be largely eliminated without detriment to efforts for conservation and maximization of ultimate recovery. However, the final rule will allow the Regional Supervisor to set production rates in cases where excessive production rates could harm ultimate recovery from the reservoir.

The final rule clarifies limits on the length of time of natural gas that may be flared or vented in certain situations. The final rule requires approval from the Regional Supervisor to flare or vent natural gas except for situations that are described in the rule. The situations that don't require Regional Supervisor approval (provided the activities are completed within a specific time frame in most cases) include:

(1) When the gas is lease use gas (produced natural gas which is used on or for the benefit of lease operations such as gas used to operate production facilities) or is used as an additive necessary to burn waste products, such as H_2S.

(2) During the restart of a facility that was shut in because of weather conditions, such as a hurricane.

(3) During the blow down of transportation pipelines downstream of the royalty meter.

(4) During the unloading or cleaning of a well, drill-stem testing, production testing, other well-evaluation testing, or the necessary blow down to perform these procedures.

(5) When properly working equipment yields flash gas (natural gas released from liquid hydrocarbons as a result of a decrease in pressure, an increase in temperature, or both) from storage vessels or other low-pressure production vessels, and you cannot economically recover this flash gas.

(6) When the equipment works properly but there is a temporary upset condition, such as a hydrate or paraffin plug.

(7) When equipment fails to work properly, including equipment maintenance and repair, or when you must relieve system pressures.

We explain the length of time that gas may be flared or vented for each situation and clarify when approval from the Regional Supervisor is required. Regardless of the reason for flaring or venting natural gas, the lessee or operator must report the amounts to MMS. The final rule requires separate reporting of the amount of natural gas flared and the amount of natural gas vented. This separate reporting requirement is in response the GAO report recommending that MMS collect these numbers separately. The MMS will publish the raw data on our Web site, along with other oil and natural gas production data. The Department of Energy's Energy Information Administration uses this production data for their statistics and analysis. This requirement will improve the quality of the data that is available on natural gas emissions.

The final rule clarifies required information submittals to MMS, including requirements relating to the documents submitted to MMS and the timing of those submissions. For example, there are additional requirements on notifying adjoining operators regarding production within 500 feet of a common lease or unit line. The final rule provides more detail as to when the notification must occur, what the notice must include, and how to verify the notification with MMS.

There are several Notices to Lessees (NTLs) that will be rescinded when the final rule becomes effective. However, if necessary, MMS will issue additional NTLs to provide guidance. We will rescind the following NTLs:

- NTL No. 97–16, *Production Within 500 Feet of a Unit or Lease Line,* effective August 1, 1997.
- NTL No. 98–23, *Interim Reporting Requirements for 30 CFR part 250, subpart K, Oil and Gas Production Rates,* effective October 15, 1998.
- NTL No. 99–G20, *Downhole Commingling Applications,* effective September 7, 1999.
- NTL No. 2006–N06, *Flaring and Venting Approvals,* effective December 19, 2006.

This NTL also provides contact information for each Region and provides sample field records. These two items are not addressed in the final rule. The MMS will issue a new NTL to include only this information, after the effective date of this final rule.

GAO Report

In July 2004, the GAO issued a report on world-wide emissions from vented and flared natural gas titled, *Natural Gas Flaring and Venting—Opportunities to Improve Data and Reduce Emissions* (GAO–04–809). This report is available on the GAO Web site at: *http://www.gao.gov/new.items/d04809.pdf*. This report reviewed the flaring and venting data available, the extent of flaring and venting, their contributions to greenhouse gas emissions, and opportunities for the Federal Government to reduce flaring and venting.

The report concluded that more accurate records are needed on flaring and venting to determine the amount of the resource that is lost and the volume of greenhouse gas emissions these practices contribute to the atmosphere each year. The report also stated that the impact of methane (a naturally occurring gas released during venting) on the earth's atmosphere is about 23 times greater than that of carbon dioxide (a byproduct of flaring). The GAO made two recommendations to the Secretary of the Interior: (1) Consider the cost and benefit of requiring that companies flare the natural gas, whenever possible, when flaring or venting is necessary; and (2) consider the cost and benefit of requiring that companies use flaring and venting meters to improve oversight. In addition, there was a recommendation to the Secretary of Energy to consider consulting with EPA (Environmental Protection Agency), MMS, and BLM (Bureau of Land Management), on how to best collect separate statistics on flaring and venting.

The MMS conducted analyses to assess the costs and benefits of requiring flare/vent meters and of requiring flaring instead of venting. The first analysis supported the recommendation to require meters, provided that the facilities process more than 2,000 barrels of oil per day (bopd). This requirement is included in the final rule.

The second analysis indicated that a regulatory change to require flaring instead of venting may be appropriate. However, the cost of implementing this requirement could be significant, and input from potentially affected parties is necessary. We requested comments on this issue in the proposed rule. Commenters pointed out that converting existing facilities that are equipped to vent natural gas to be able to flare natural gas may require significant redesign for safety. They also pointed out that there are many factors in determining whether to flare natural gas or vent natural when designing a facility. These factors include the operating philosophy, nature and type of reservoir, facility design limitations or capabilities, operating practices, safety, and economics. Industry comments were consistent in recommending that in addition to the considering requiring flaring instead of venting, that MMS work with them to find ways to reduce overall natural gas emissions. They also stated that a

requirement for flaring instead of venting should be only for new facilities. They requested that MMS hold a workshop to discuss the issue. The MMS plans to work directly with interested parties to study the costs and benefits of requiring that companies flare the natural gas, whenever possible, when flaring or venting is necessary, as recommended in the GAO report. We will hold a workshop to discuss the issue of flaring instead of venting, shortly after this final rule is published. This workshop and additional cost-benefit analysis will consider greenhouse gas issues associated with flaring and venting. The workshop will be the first step in considering how to best implement this recommendation. The MMS will decide how to move forward with the rulemaking on flaring natural gas after we hold the workshop. Our next step would likely be an advance notice of proposed rulemaking to further vet our approach with industry and other stakeholders.

To improve data collection, as the GAO report suggested, MMS will require operators to report flaring and venting volumes to MMS separately. Previously, MMS only collected information on the total natural gas flared and vented. Operators did not need to differentiate between the two categories.

Oil and Gas Industry Contributions to Greenhouse Gases in the Federal OCS

Most natural gas production involves extracting natural gas from wells drilled into underground gas reservoirs; however, some natural gas is generated as a by-product of oil production. During oil and natural gas production it may become necessary to burn or release natural gas for a number of operational reasons, including safety. These operations may be associated with unloading or cleaning of a well, production testing, or relieving system pressure during equipment failure. The controlled burning of natural gas is called flaring, while the controlled release of unburned gases directly into the atmosphere is called venting. Most flaring and venting occurs at the end of a flare stack or boom which ensures that natural gas can be safely disposed of in emergency and shutdown situations. It is virtually impossible to produce oil and natural gas without any flaring or venting and it would be impractical to shut in production every time an upset occurs. It is estimated that operators in the Gulf of Mexico Outer Continental Shelf (OCS) flare and vent less than 0.5 percent of the gas produced, making this area a world leader in the conservation of natural gas resources.

Both flaring and venting on the OCS are highly regulated by the Minerals Management Service (MMS). Federal regulations (30 CFR 250, Subpart K) specify the limited circumstances under which offshore oil and gas operators may flare or vent natural gas. These final regulations strictly limit the amount of time operators may flare or vent. In some cases, operators request additional time in order to complete equipment repairs. We evaluate each of these requests on a case-by-case basis, with conservation as a primary focus.

Even though they are already a world leader, MMS continuously strives to improve our oversight of OCS flaring and venting. In most places around the world, for example, there is minimal reporting or tracking of flare and/or vent volumes. In the Federal OCS, MMS requires operators to continuously record these volumes and report them each month. These final regulations will require operators to install flare/vent meters on large platforms and also to report gas flared separately from gas vented. These regulatory changes would provide more accurate measurements of GHG emissions.

Given the existing restrictions on OCS flaring and venting, there is minimal opportunity to further reduce the overall volume of gas flared and vented. However, the global warming potential (GWP) of GHG emissions could be reduced if MMS were to require operators to flare instead of vent (when the release of natural gas is necessary). Such a requirement would reduce the GWP of GHG emissions by converting most methane to carbon dioxide as it is released. As previously stated, MMS is planning a workshop to address this topic.

It is difficult to estimate the impact that flaring instead of venting would have on GHG emissions until we begin to gather more accurate data from the requirement to install flare/vent meters and to report flare volumes separately from vent volumes. Furthermore, it is impractical, if not impossible, to eliminate all venting. Even if 100% of the released OCS gas could be flared instead of vented, the impact on total U.S. GHG emissions would be very small.

In 2005, U.S. greenhouse gas (GHG) emissions totaled 7.986×10^9 tons of carbon dioxide equivalent (CO_2e). Of that total, only 24.7×10^6 tons of CO_2e, or 0.31 percent, were related to OCS oil and gas production (including platform and non-platform sources), flaring and venting activities represent only a fraction of that amount. Under MMS oversight, OCS oil and gas operators are already ahead of the curve in terms of limiting GHG emissions.

Based on several assumptions, estimates, and existing analyses, MMS roughly approximated the impact that might occur if it were to mandate flaring over venting. These estimates indicate that such a requirement would reduce total US GHG emissions by less than 0.05%. However, the accuracy of these estimates will improve after the regulatory change becomes final. Reported OCS flare and vent volumes could increase or decrease based solely on improved reporting accuracy. In any event, further analysis may shed light on whether flaring rather than venting natural gas is cost effective from a greenhouse gas perspective, even if the total amount of greenhouse gases is small.

Public Comments on the Proposed Rule

The MMS received eight sets of comments on the NPR from industry trade groups and representatives and one comment from the State of Alaska. The MMS reviewed and responded to these comments as appropriate. To help convey the comments, we summarized and combined similar comments. The results are explained in the following two tables. Table 1 contains our responses to general comments and Table 2 addresses comments on specific sections.

TABLE 1—MMS RESPONSE TO GENERAL COMMENTS

Comment	MMS response
Measurement	
(1) Measurement accuracy for flared or vented gas envisioned by rule is not achievable given the wide range of conditions to which the meter would be exposed.	The MMS agrees. We will revise the accuracy requirement from 2 percent to 5 percent. This is established technology in the North Sea and Canada, and a 5 percent accuracy requirement has been adopted by regulatory bodies in those regions. Also, flare/vent meters with this accuracy are already used on some Gulf of Mexico (GOM) facilities.
(2) Retrofitting may be a problem due to space limitations and safety concerns.	Installation of meters is necessary to improve oversight of MMS's flare/vent program. A cost-benefit analysis conducted by MMS supports GAO's recommendation to install meters on all facilities that process more than 2,000 bopd. The Regional Supervisor will work with operators on a case-by-case basis if a safety or space issue is demonstrated, as a departure under § 250.142.
(3) If deferment of this part of the rule is not acceptable, it is recommended that meters be limited to new facilities under construction 6 months after date that final rule is published.	Installation of meters is necessary to improve oversight of MMS's flare/vent program. The cost-benefit analysis concluded that meters on all facilities processing over 2,000 bopd is appropriate, not just new facilities. Also, metering flare/vent volumes on all (existing and future) facilities processing over 2,000 bopd better implements the GAO recommendations.
(4) Defer requirement to install meters on all offshore complexes processing 2,000 bopd to develop a best practice with industry that would have broad applicability to all facilities on the OCS, not just those processing 2,000 bopd.	The MMS has sufficient information to finalize the rule. Additional input from industry groups is not necessary and would delay implementation of GAO recommendations. We agree that there should be a best practice established for estimating volumes of gas flared or vented from facilities processing less than 2,000 bopd. However, metering is more accurate, and requiring meters on those facilities that process more than 2,000 bopd is consistent with the GAO recommendations.
(5) The number of facilities impacted by the rule has been underestimated since multiple facilities may be involved in processing/handling production streams.	The commenter did not provide an alternate, documented number; therefore, MMS must use our best analysis.
(6) Cost impact of the rule has been underestimated.	A higher cost estimate was provided by the commenter. We used the cost model that was submitted by the commenter in our cost-benefit analysis and determined that the difference is negligible and that a 2,000 bopd threshold for metering is still appropriate.
(7) Set a thousand cubic feet (MCF) volume per day vented, calculated by test, rather than having a mandatory metering system.	Volume estimates calculated from a test are far less accurate than metered volumes and would not achieve the improvements recommended by GAO.
(8) These meters should not be subject to the requirements of Subpart L.	Flare/vent meters are subject to the requirements of Subpart K.
(9) Cost is a huge burden to smaller facilities; increase meter requirement to facilities with average throughput of 10,000 bopd or more.	See responses (2) and (6). Also see discussion concerning the Regulatory Flexibility Act.
(10) Revise time to install meters from 120 days to 180 days to accommodate design, shipping, and labor.	The MMS agrees. We will revise the time allowed to install meters from 120 to 180 days for facilities processing more than 2,000 bopd when this final rule becomes effective. The time allowed to install meters on facilities that begin producing above 2,000 bopd, after this final rule is published, will also be revised from 90 to 120 days.
(11) Revise accuracy to 15 percent.	The MMS disagrees. See response (1).
(12) Meter high flow events, calculate others.	The MMS disagrees. See response (2).
(13) What if we don't have a flow when we schedule a calibration? Most of our flaring/venting is done during upset or emergency situations. Flare pilot must be kept on at all times, hence, inert gas such as nitrogen cannot be used as it will pose a safety issue by extinguishing the pilot flame.	At a minimum, calibration/verification of secondary devices associated with flare/vent meters can be performed in a no-flow situation in accordance with American Petroleum Institute's (API) Manual of Petroleum Measurement Standards (MPMS) Chapter 14 Section 10. Also, contingent upon the meter type, verification may include the performance of manufacturer recommended inspections and diagnostics. However, after further review, we determined that calibrating meters once a year is adequate.
(14) The time required to bring an existing facility into compliance would far exceed 120 days.	The MMS agrees. See response (10).
(15) Establish best practices for existing facilities to reduce overall levels of gas vented/flared.	The limits on flaring and venting set by these regulations are minimal, additional reductions in the levels of natural gas flared or vented would not reduce the need for meters. However, MMS does agree that industry should establish best practices for reducing the amount of natural gas flared or vented and we will include this topic as part of the flaring and venting workshop we are planning.
(16) Multiple meters would be required on most facilities.	The MMS anticipates 2 or 3 meters on most facilities where meters are required. That is, one for each pressure system (High Pressure (HP), Intermediate Pressure (IP), and Low Pressure (LP)) that exists on the facility. The meters would likely be located near the base of the flare boom just before the piping for that pressure system exits the facility.

TABLE 1—MMS RESPONSE TO GENERAL COMMENTS—Continued

Comment	MMS response
(17) Wait for completion of API RP on measurement and allocation.	The MMS has sufficient information to finalize the rule. As API Recommended Practices (RP) are published, MMS will consider incorporating these into our regulations.
(18) Future workshop should be planned to discuss solutions and best practices.	The MMS will hold a workshop after this final rule is issued. This will be included as a topic as part of our workshop on flaring and venting.
(19) Where did 2,000 bopd come from?	The MMS conducted a cost-benefit analysis looking at equipment costs, gas prices, and platform life to determine a minimum production rate that could support the installation of flare/vent meters. Also see Regulatory Flexibility Act discussion.
Flaring/Venting	
(20) Converting to flare on existing facilities may require redesign for safety.	The MMS is still evaluating the flare versus vent issue and will hold an industry workshop to collect additional information.
(21) Limiting the flaring or venting of gas-well gas to 2 hours and allowing 48 continuous hours for oil-well gas when a hydrate plug forms is not consistent with prior guidance and actions. Previous MMS guidance made no distinction between gas-well gas and oil-well gas if the plug (hydrate) formed naturally.	We have always distinguished between gas-well gas and oil-well gas. The prior regulation stated that "lessees must not flare or vent gas-well gas beyond the time required to eliminate an emergency unless the Regional Supervisor approves." MMS policy has consistently been to allow 2 hours to eliminate the flare or vent under this rule. We added an exception for hydrate plugs under § 250.1160(a)(6).
(22) Short comment period for response did not allow industry to develop detailed comments on flaring versus venting.	The MMS included information in the preamble on the flaring versus venting issue because it was addressed in the GAO report, and we wanted operators to be aware that MMS is considering possible changes to the regulations to address this issue in the future. The MMS is still evaluating this issue and we may hold a workshop to collect additional information, before proposing new regulations on this issue.
(23) Retain records for 2 years instead of 6 years.	There was no change proposed here; this is merely a clarification that existing law (30 U.S.C. 1713, implemented at 30 CFR part 212) applies to flare/vent records. Those records must be maintained for 6 years (in accordance with 30 U.S.C. 1713 and 30 CFR part 212), in addition to being maintained on the facility for 2 years and available for inspection by MMS personnel.
Miscellaneous	
(24) How much of the MMS budget is being supported by the cost recovery program at this time; is an evaluation of the fee structure being carried out to adjust for actual agency needs?	The total discretionary budget for MMS in Fiscal Year 2007 was $288.2 million. Total revenue generated by cost recovery fees that year totaled $11.9 million or 4.1 percent of the total MMS discretionary budget. The MMS recently adjusted these fees by the Implicit Price Deflator for the Gross Domestic Product, as provided by regulation. The MMS plans to review cost recovery fees in the coming year. Should this review result in a need to change the fees significantly, rulemaking will be required and a proposed rule will be published in the **Federal Register** for public review and comment. Fees are established in accordance with the Independent Offices Appropriation Act of 1952, 31 U.S.C. 9701. It should be noted that MMS does not determine or adjust cost recovery fees to meet a predetermined funding target, but rather to reflect the cost of actual services provided.
(25) The OOC, in conjunction with API, will commit to the development of a technical document or RP that would address quantification, including volume, mass, and composition of flare and vent quantities within the oil and gas production process. The OOC proposes to start working on this document now, concurrent with the subpart K final rulemaking; document and workshops to industry could occur within 18 months.	The MMS has sufficient information to finalize this final rule. As API RPs are published, MMS will consider incorporating these into our regulations.
(26) For the protection of the State of Alaska's correlative rights, require approval for operators to produce within 500 ft of a lease or unit line even if adjacent acreage is unleased, allow State to comment.	The MMS does not agree that this final rule violates State correlative rights. The MMS understands the State of Alaska's interest in protecting its correlative rights in the event of development and production from an OCS lease adjacent to State unleased lands. Under the MMS regulatory process, the State of Alaska will receive and will have the opportunity to comment on each OCS Development and Production Plan (DPP) (30 CFR part 250 subpart B). A DPP will include information on surface and bottom hole locations to enable the State of Alaska to determine if its correlative rights are at risk. The State of Alaska is entitled to copies of the Application(s) for Permit to Drill (APD) to monitor and assure that activities are conducted in accordance with an approved DPP.

TABLE 2—MMS RESPONSE TO COMMENTS ON SPECIFIC REQUIREMENTS

Citation/comment	MMS response
§ 250.1153(b)(2)—Consider completions with downhole gauges instead of requiring bottomhole pressure surveys.	The MMS is not implementing this suggestion in the final rule. This configuration results in a single pressure measurement, which is not a survey. A survey is required in order to establish a pressure gradient, which is used to correct reservoir pressures to a common datum. As stated in § 250.1153(d), industry may continue to request departures from this requirement, if necessary.
§ 250.1160(a)—Add gas-well flash gas	Wording in the final rule will change from *oil-well gas or gas-well gas* to *natural gas.* This wording covers the venting or flaring of all natural gas regardless of the well type.
§ 250.1160(a)(3)(i)—Neither lease nor pipeline operator needs MMS approval to blowdown pipelines downstream of royalty meters.	The commenter is correct, approval under this subpart will not be required for this situation since the activity is downstream of the royalty meter; however, flaring or venting must be reported after the fact in accordance with this final rule. Approvals may be required under subparts H and J of this part.
§ 250.1160(a)(4)—Include unloading or cleaning of a well in addition to testing under the *Additional requirements* column.	The MMS agrees. The wording was modified to be consistent with the *Condition* column.
§ 250.1160(a)(5)—Define the amount of routine flaring or venting that is considered uneconomic.	Since economic conditions vary with time, MMS cannot specify a fixed volume higher than 50 MCF per day. The *Additional requirements* column clearly indicates that a monthly average volume equal to 50 MCF per day or less is assumed by MMS to be uneconomic. If your facility averages more than 50 MCF per day, you will be expected to capture the gas or demonstrate that the volume is uneconomic and continue to monitor the economic viability as costs and prices change.
§ 250.1160(a)(6)—The time necessary to unload a well after an upset is remedied should be granted under § 250.1160(a)(4) and should not be included in the 48 continuous hours or 144 cumulative hours allowed under § 260.1160(a)(6) (*upset due to hydrate plugs, etc.*).	The initial cause of the problem will determine where the incident falls (either § 250.1160(a)(2), (a)(4), (a)(6), or (a)(7)). For example, an operator may flare oil-well gas without prior approval for 48 continuous hours in order to remediate a hydrate plug. However, that operator may not continue to flare without approval for an additional 48 hours in order to unload the well after the hydrate plug is remediated. In this example, the initial cause of the problem was a hydrate plug; therefore, the operator will only be authorized to flare oil-well gas for up to 48 continuous hours without approval (under § 250.1160(a)(6)).
§ 250.1160(a)(7)—The cumulative time allowed in paragraph (a)(4) should also be included in (a)(7)(iv). The hours accumulated to restore/optimize production should not impact the hours accrued due to equipment failures.	The initial cause of the problem will determine where the incident falls (either § 250.1160(a)(2), (a)(4), (a)(6), or (a)(7)) and therefore the time allotted to perform the work related to the incident. If an equipment failure results in a need to flare or vent under § 250.1160(a)(7), any additional procedures needed to restore production (e.g., well blow down), must be performed within the time allotted under § 250.1160(a)(7). The operator would need to request approval from the Regional Supervisor if additional time is needed.
§ 250.1160(b)—Subpart C is sufficient to regulate pollution issues, mentioning Subpart C in Subpart K is redundant and confusing. Production upsets are not anticipated and therefore would not lend themselves to prior approval.	The MMS agrees that it is not necessary to mention subpart C in subpart K. The MMS also agrees that production upsets may not lend themselves to prior approval. Paragraph (a) details the periods allowable during production upsets before MMS approval is required. Regardless of whether or not operators need and receive prior approval under (a), however, they are still obligated to follow their approved Development Operations Coordination Document (DOCD) or DPP under subpart B. We reworded § 250.1160(b) to clarify that MMS flare or vent approvals granted under subpart K do not exempt operators from the requirement to follow their DOCD or DPP. Before flaring and/or venting an amount that exceeds the limits specified in their DOCD or DPP, operators must submit and receive approval of a revised DOCD or DPP.
§ 250.1160(e)—If MMS approves flaring or venting, the volume should not be considered avoidably lost unless information provided was incorrect. Revise wording to state RS will evaluate flaring and venting requests to determine if situation exceeds those in § 250.1160(a).	The subject paragraph was eliminated since negligence related to flaring and venting is adequately covered in the subsequent paragraph.
§ 250.1160(f)—If MMS approves flaring or venting, the volume should not be considered avoidably lost unless information provided was incorrect. Revise wording to state flaring or venting in excess of situations in § 250.1160(a) without approval, or if approval was obtained with misleading information, will be considered avoidably lost.	Additional wording referencing § 250.1160(a) is not necessary. Although MMS does not intend to commonly determine gas to be avoidably lost after we have approved the flaring or venting, the Regional Supervisor must retain full authority to make that determination.
§ 250.1161(c)—Industry supports addressing small leaks from valves, etc., if all safety concerns are addressed.	The MMS agrees. Small leaks from valves, fittings, flanges, pressure relief valves or similar components are considered fugitive emissions and are more appropriately addressed under 30 CFR 250.107 ("What must I do to protect health, safety, property, and the environment?"). Note that this paragraph was reworded and renumbered as 30 CFR 250.1160(f).
§ 250.1162(a)—Include all liquid hydrocarbons, not just condensate.	The MMS agrees. The word condensate will be replaced with liquid hydrocarbons.

TABLE 2—MMS RESPONSE TO COMMENTS ON SPECIFIC REQUIREMENTS—Continued

Citation/comment	MMS response
§ 250.1163(a)—Metering—defer this part until a workshop can be held with industry; work in conjunction with API to develop a Technical Bulletin; not enough time to retrofit existing facilities; high degree of measurement accuracy is unrealistic; if not deferred, limit to new facilities; and pulling a portion of the metering requirement may conflict with the Administration and Procedures Act.	The MMS has sufficient information to finalize this rule. Additional input from industry groups is not necessary and would delay implementation of GAO recommendations. The meter accuracy requirement has been changed from 2 percent to 5 percent. We changed the time to install the meters on existing facilities from 120 days to 180 days based on an industry comment. Thus rulemaking is consistent with the Administrative Procedure Act (5 U.S.C. § 553, Rulemaking).
§ 250.1163(a)(3)—OGOR–B submitted to MRM will not accommodate multiple facility submissions. Flared or vented gas at a host facility would have to be allocated back to the lease.	Note—The proposed rule did not have a § 250.1163(a)(3), this comment presumably refers to § 250.1163(b)(3). The MMS agrees that modified reporting on Form MMS–4054 Part B (OGOR–B) is required in order to implement this GAO recommendation. In order to implement this, § 250.1163(a)(1) of the final rule will require operators to notify MMS of all facilities that process more than 2,000 bopd and therefore require meters. The Regional Supervisor will then establish Facility Measurement Point (FMP) numbers for those metering locations. These FMP numbers will be used on the OGOR–B forms to identify the facilities where flaring and venting occurs. Further, in order to ease the reporting burden, the language will be modified from that in the proposed rule. Instead of requiring operators to associate all flared and vented volumes with the facilities where the flaring and venting occurred, such reporting (on OGOR–B forms) is only required for those facilities which are required to install flare/vent meters (§ 250.1160(b)(3)). For other facilities, operators must continue to report flared and vented volumes by lease or unit (§ 250.1163(b)(4)) (note that flared and vented volumes must be separated regardless of whether reporting is by facility, lease, or unit). Additionally, MRM will send guidance to operators on all other reporting requirements necessitated by this regulatory change.
§ 250.1163(b)(1)—Reporting separate flaring or venting on OGOR B will require modification to current reporting requirements.	See response § 250.1163(a)(3).
§ 250.1163(b)(2)—Lease use already reported on OGOR B.	The MMS agrees. Section 250.1163(b)(2) requires reporting lease use gas on Form MMS–4054, which is the OGOR. This rule does not impose additional lease use reporting requirements. The wording was modified slightly to clarify this issue.
§ 250.1163(b)(3)—Reporting flaring or venting from multiple facilities separately on a single lease is redundant and requires changes from industry and MRM. These records are kept at each facility and could be requested from the operator as needed to eliminate this burdensome requirement.	See response § 250.1163(a)(3).
§ 250.1163(c)—Industry sends a letter summarizing pertinent flaring or venting information after receiving oral approval to flare or vent; requiring actual flaring or venting records be kept on location is redundant.	The MMS disagrees. Summary information submitted in a letter following an oral approval is only a portion of the required records to be saved on location. A complete record must be maintained on each facility for routine inspections by MMS personnel.
§ 250.1164(b)(1)—Subpart C is sufficient to regulate pollution issues.	The MMS agrees. This paragraph was deleted.
§ 250.1167–General—Requiring the following additional information is burdensome and redundant to data previously submitted in other documents (e.g. CIDs). § 250.1167(a)(3)—net sand isopach. § 250.1167(a)(4)—net hydrocarbon isopach. § 250.1167(b)(2)—amplitude maps. § 250.1167(d)(1)—estimated recoverable reserves for each completion in a reservoir. § 250.1167(e)(2)—reservoir name and whether it is competitive.	Data submitted for an early application would often be obsolete interpretations and result in inaccurate conclusions. Furthermore, receiving the data in separate submittals will expedite MMS review of industry applications.

After reviewing and responding to the comments, MMS changed the appropriate rule language as specified in the MMS comment response. Table 3 compares the changes from the NPR to this final rule.

TABLE 3—CHANGES FROM THE PROPOSED RULE TO THIS FINAL RULE

Citation—description, or reason for the change	Proposed rule language	Final rule language
§ 250.105—Removed the phrase "in the field" from the definition of *Flaring.* This phrase is not necessary, since all activities under this regulation take place in the field. Also, changed "gas" to "natural gas" for clarity.	*Flaring* means the burning of gas in the field as it is released into the atmosphere.	*Flaring* means the burning of natural gas as it is released into the atmosphere.

TABLE 3—CHANGES FROM THE PROPOSED RULE TO THIS FINAL RULE—Continued

Citation—description, or reason for the change	Proposed rule language	Final rule language
§ 250.105—Revised the definition of *Sensitive reservoir* to state that it is a reservoir in which the production rate will affect ultimate recovery. This is a more accurate and inclusive definition.	*Sensitive reservoir* means a reservoir in which high reservoir production rates will decrease ultimate recovery.	*Sensitive reservoir* means a reservoir in which the production rate will affect ultimate recovery.
§ 250.1150—Revised wording back to the text in the existing rule, changed "without harming ultimate recovery" to "while maximizing ultimate recovery". This wording is more consistent with our mission and with the requirements of the final rule.	You must produce wells and reservoirs at rates that provide for economic development without harming ultimate recovery and without adversely affecting correlative rights.	You must produce wells and reservoirs at rates that provide for economic development while maximizing ultimate recovery and without adversely affecting correlative rights.
§ 250.1151(c)—Revised language to clarify submittal requirement for the required form (either form MMS–126 or MMS–128). Three copies of the form must be submitted, one of those copies is a public information copy. A public information copy of the supporting documents is not required, therefore only two copies of the supporting information must be submitted.	You must submit an original and one copy of the form required by paragraph (a) of this section, as listed in the table in § 250.1167. You must include one public information copy with each submittal in accordance with §§ 250.190 and 250.196, and mark that copy "Public Information".	You must submit to the Regional Supervisor an original and two copies of the appropriate form required by paragraph (a) of this section; one of the copies of the form must be a public information copy in accordance with §§ 250.186 and 250.197, and marked "Public Information." You must submit two copies of the supporting information as listed in the table in § 250.1167 with form MMS–126.
§ 250.1153(d)—Clarified language on requesting a departure from conducting a static bottomhole pressure survey to specify what information must be included with the request.	The Regional Supervisor may grant a departure from the requirement to run a static bottomhole pressure survey. You must request a departure by letter, along with Form MMS–140, Bottomhole Pressure Survey Report. You must include sufficient justification to support the departure request.	The Regional Supervisor may grant a departure from the requirement to run a static bottomhole pressure survey. To request a departure, you must submit a justification, along with Form MMS–140, Bottomhole Pressure Survey Report, showing a calculated bottomhole pressure or any measured data.
§ 250.1154(a)(3)—Simplified wording—changed "secondary or tertiary" to "enhanced". The term enhanced includes secondary and tertiary recovery techniques.	The reservoir is undergoing secondary or tertiary recovery.	The reservoir is undergoing enhanced recovery.
§ 250.1154(b)—Restructured the paragraph, adding two subparagraphs.	For the purposes of this subpart, near-critical fluids are those fluids that occur in high temperature, high-pressure reservoirs where it is not possible to define the liquid-gas contact or fluids in reservoirs that are near bubble point or dew point conditions.	For the purposes of this subpart, near-critical fluids are: (1) Those fluids that occur in high temperature, high-pressure reservoirs where it is not possible to define the liquid-gas contact; or (2) Fluids in reservoirs that are near bubble point or dew point conditions.
§ 250.1155—Revised language to clarify submittal requirements for form MMS–127. Three copies of form MMS–127 must be submitted, one is a public information copy. A public information copy of the supporting documents is not required, therefore only two copies of the supporting information must be submitted.	You must submit an original and three copies of Form MMS–127 and supporting information, as listed in the table in § 250.1167 to the Regional Supervisor. You must include one public information copy with each submittal in accordance with §§ 250.190 and 250.196, and mark that copy "Public Information."	You must submit to the Regional Supervisor an original and two copies of Form MMS–127; one of the copies must be a public information copy in accordance with §§ 250.186 and 250.197, and marked "Public Information." You must also submit two copies of the supporting information, as listed in the table in § 250.1167.* * *
§ 250.1155(b)—Added language to clarify that the structure maps and well logs, required as supporting information for form MMS–127, are not required as part of the annual submittal.	At least once during the calendar year	At least once during the calendar year, but you do not need to resubmit unrevised structure maps (§ 250.1167(a)(2)) or previously submitted well logs (§ 250.1167(c)(1)).

TABLE 3—CHANGES FROM THE PROPOSED RULE TO THIS FINAL RULE—Continued

Citation—description, or reason for the change	Proposed rule language	Final rule language
§ 250.1156(a)—Clarified that approval is needed before producing from a reservoir within in a well that is less than 500 ft. from a lease line. Reworded the section to clarify instructions on submitting the service fee and supporting information. Removed the phrase, "whether it is necessary to," from the sentence on how the Regional Supervisor will determine whether to approve the request. Added the parenthetical phrase record title and operating rights to clarify the meaning of lease interest and to be consistent with the definition of lessee in 30 CFR part 250 subpart A.	You must obtain approval from the Regional Supervisor before you start producing from a well that has any portion of the completed interval less than 500 feet from a unit or lease line. Submit to MMS the service fee listed in § 250.125 and the Regional Supervisor will determine whether approval of your request will maximize ultimate recovery, avoids the waste of natural resources or whether it is necessary to protect correlative rights. You do not need to obtain approval if the adjacent leases or units have the same unit, lease, and royalty interests as the lease or unit you plan to produce. You do not need to obtain approval if the adjacent block is unleased.	You must obtain approval from the Regional Supervisor before you start producing from a reservoir within a well that has any portion of the completed interval less than 500 feet from a unit or lease line. Submit to MMS the service fee listed in § 250.125, according to the instructions in § 250.126, and the supporting information, as listed in the table in § 250.1167, with your request. The Regional Supervisor will determine whether approval of your request will maximize ultimate recovery, avoid the waste of natural resources, or protect correlative rights. You do not need to obtain approval if the adjacent leases or units have the same unit, lease (record title and operating rights), and royalty interests as the lease or unit you plan to produce. You do not need to obtain approval if the adjacent block is unleased.
§ 250.1157—Added wording to state that the Regional Supervisor will determine whether the request to produce gas-cap-gas from an oil reservoir maximizes ultimate recovery. This informs the applicant of the basis for the decision to approve or disapprove the request. We also restructured the section to improve readability.	You must request and receive written approval from the Regional Supervisor before producing gas from each completion in an oil reservoir that is known to have an associated gas cap. If the oil reservoir is not initially known to have an associated gas cap, but your oil well begins to show characteristics of a gas well, you must request and receive written approval from the Regional Supervisor to continue producing the well. You must include the service fee listed in § 250.125 and the supporting information, as listed in the table in § 250.1167, with your request.	(a) You must request and receive approval from the Regional Supervisor: (1) Before producing gas-cap gas from each completion in an oil reservoir that is known to have an associated gas cap. (2) To continue production from a well if the oil reservoir is not initially known to have an associated gas cap, but the oil well begins to show characteristics of a gas well. (b) For either request, you must submit the service fee listed in § 250.125, according to the instructions in § 250.126, and the supporting information, as listed in the table in § 250.1167, with your request. (c) The Regional Supervisor will determine whether your request maximizes ultimate recovery.
§ 250.1158(b)—Changed "commingled" to "proposed for commingling," since the reservoirs are only proposed for commingling at this stage of the process.	If one or more of the commingled reservoirs is a competitive reservoir, you must notify the operators of all leases that contain the reservoir that you intend to downhole commingle the reservoirs.	If one or more of the reservoirs proposed for commingling is a competitive reservoir, you must notify the operators of all leases that contain the reservoir that you intend to downhole commingle the reservoirs.
§ 250.1159(b)—Changed "or" to "and/or."	If the Regional Supervisor sets an MPR for a producing well completion, or an MER for a reservoir, you may not exceed those rates except due to normal variations and fluctuations in production rates, as set by the Regional Supervisor.	If the Regional Supervisor sets an MPR for a producing well completion and/or an MER for a reservoir, you may not exceed those rates except due to normal variations and fluctuations in production rates as set by the Regional Supervisor.
§ 250.1160(a)—Per industry comment, we changed oil-well gas or gas-well gas to natural gas. This wording covers the venting or flaring of all natural gas regardless of the well type.	You must receive approval from the Regional Supervisor to flare or vent oil-well gas or gas-well gas at your facility, * * *	You must request and receive approval from the Regional Supervisor to flare or vent natural gas at your facility,
§ 250.1160(a)(4), *Additional requirements* column—Per industry comment, we added during unloading or cleaning of a well to make wording consistent with wording under the *Condition* column.	You may not exceed 48 cumulative hours of flaring or venting per testing operation on a single completion without Regional Supervisor approval.	You may not exceed 48 cumulative hours of flaring or venting per unloading or cleaning or testing operation on a single completion without Regional Supervisor approval.
§ 250.1160(b)—Per industry comment, we simplified the wording and clarified that the operators are accountable for estimated maximum flare/vent volumes provided to MMS in DPPs and DOCDs and removed reference to 30 CFR part 250 subpart C.	You must inform the Regional Supervisor and receive approval to flare or vent gas before you exceed the volume specified in your DPP submitted under subpart B of this part, even if the flaring or venting does not require approval under paragraph (a) of this section. The Regional Supervisor will determine whether your proposed flaring or venting complies with air emission thresholds under subpart C of this part.	Regardless of the requirements in paragraph (a) of this section, you must not flare or vent gas over the volume approved in your Development Operations Coordination Document (DOCD) or your Development and Production Plan (DPP).
§ 250.1160(e)—Per industry comment, we deleted this paragraph and renumbered the section, since negligence in flaring or venting of gas is covered in § 250.1160(f).	The Regional Supervisor will evaluate your request for gas flaring or venting and determine if the loss of hydrocarbons is due to negligence, or could be avoided.	Deleted entire paragraph.

TABLE 3—CHANGES FROM THE PROPOSED RULE TO THIS FINAL RULE—Continued

Citation—description, or reason for the change	Proposed rule language	Final rule language
§ 250.1161—Revised introductory paragraph to improve clarity.	You may flare or vent oil-well gas and gas-well flash gas for a period that the Regional Supervisor will specify, and which will not exceed 1 year, if the Regional Supervisor approves your request for one of the following reasons:	You must request and receive approval from the Regional Supervisor to flare or vent gas for an extended period of time. The Regional Supervisor will specify the approved period of time, which will not exceed 1 year. The Regional Supervisor may deny your request if it does not ensure the conservation of natural resources or is not consistent with national interests relating to development and production of minerals of the OCS. The Regional Supervisor may approve your request for one of the following reasons:
§ 250.1161(c)—Moved to § 250.1160(f). Clarified how MMS will handle small emissions that are not caught by a capture system. Emissions that occur from leaking valves, fittings, flanges, pressure relief valves and similar components, are considered fugitive emissions. These emissions are more appropriately addressed under safety regulations than conservation regulations. Section 250.1161(c) was renumbered to § 250.1160(f) because this paragraph provides general guidance to operators and is therefore more appropriately listed under § 250.1160.	§ 250.1161(c) The Regional Supervisor determines that an improperly working valve, pipe fitting, or similar component results in flaring or venting of less than 10 MCF per day, and that it is prudent to repair the leak at a later date. The Regional Supervisor may exempt this flaring or venting from the time limits set in § 250.1160.	§ 250.1160(f) Fugitive emissions from valves, fittings, flanges, pressure relief valves or similar components do not require approval under this subpart unless specifically required by the Regional Supervisor.
§ 250.1162(a)—Per industry comments, we replaced the term *condensate* with *liquid hydrocarbons* to allow burning of oil in limited cases. In addition, we deleted the statement "In most cases, the Regional Supervisor will not allow you to burn more than 300 barrels of condensate in total during unloading or cleaning of a well, drill-stem testing, production testing, or other well-evaluation testing." We decided it is better to make this decision on a case-by-case basis. Also changed "feasible" to "technically feasible."	You must request and receive approval from the Regional Supervisor to burn any produced liquid hydrocarbons. The Regional Supervisor may allow you to burn condensate if you demonstrate that transporting it to market or re-injecting it is not feasible or poses a significant risk of harm to offshore personnel or the environment. In most cases, the Regional Supervisor will not allow you to burn more than 300 barrels of condensate in total during unloading or cleaning of a well, drill-stem testing, production testing, or other well-evaluation testing.	You must request and receive approval from the Regional Supervisor to burn any produced liquid hydrocarbons. The Regional Supervisor may allow you to burn liquid hydrocarbons if you demonstrate that transporting them to market or re-injecting them is not technically feasible or poses a significant risk of harm to offshore personnel or the environment.
§ 250.1162(b)—We eliminated this paragraph and renumbered the subsequent paragraph because this is covered in § 250.1162(c).	The Regional Supervisor will evaluate your request for liquid hydrocarbon burning, and determine if the loss of hydrocarbons is due to negligence or could be avoided.	Paragraph deleted and subsequent paragraph renumbered.
§ 250.1163(a)—Per industry comments, we changed the requirement to install meters on facilities that already process more than 2,000 bopd from 120 days after the rule is published to 180 days after the rule is effective. Per industry comments, we changed the requirement to install meters on facilities that begin to process more than 2,000 bopd, after the rule is effective, from 90 days to 120 days after the facility begins to process more than the 2,000 bopd.	If your facility processes more than an average of 2,000 bopd during May 2010, you must install flare/vent meters within 120 days after May 2010. If your facility processes more than an average of 2,000 bopd during a calendar month after May 2010, you must install flare/vent meters within 90 days after the end of the month in which the average amount of oil processed exceeds 2,000 bopd.	If your facility processes more than an average of 2,000 bopd during May 2010, you must install flare/vent meters within 180 days after May 2010. If your facility processes more than an average of 2,000 bopd during a calendar month after May 2010, you must install flare/vent meters within 120 days after the end of the month in which the average amount of oil processed exceeds 2,000 bopd.
§ 250.1163(a)(1)—Per industry comment, we added a new paragraph to require a one-time notification to the Regional Supervisor if a facility processes more than 2,000 bopd. This will trigger FMP assignments to simplify reporting. We renumbered the subsequent paragraphs.	No language proposed	You must notify the Regional Supervisor when your facility begins to process more than an average of 2,000 bopd in a calendar month.
§ 250.1163(a)(2)—Per industry comment, we revised the accuracy requirement from 2 percent to 5 percent. This is established technology in the North Sea and Canada, and a 5 percent accuracy requirement has been adopted by regulatory bodies in those regions. Also, flare/vent meters with this accuracy are already used on some Gulf of Mexico facilities.	The flare/vent meters must measure all flared and vented gas within 2 percent accuracy.	The flare/vent meters must measure all flared and vented gas within 5 percent accuracy.

TABLE 3—CHANGES FROM THE PROPOSED RULE TO THIS FINAL RULE—Continued

Citation—description, or reason for the change	Proposed rule language	Final rule language
§ 250.1163(a)(3)—Per industry comment, we changed the calibration requirement from at least once every 6 months to at least once every year.	You must calibrate the meters regularly, in accordance with the manufacturer's recommendation, or at least once every 6 months, whichever is shorter.	You must calibrate the meters regularly, in accordance with the manufacturer's recommendation, or at least once every year, whichever is shorter.
§ 250.1163(a)(4)—Added a new paragraph to clarify that meters should not be removed if the amount of oil the facility processes later drops below 2,000 bopd.	No language proposed	You must use and maintain the flare/vent meters for the life of the facility.
§ 250.1163(b)(2)—Simplified wording from, "gas used as pilot lights, instrument gas, purge gas used to prevent oxygen from entering the flare or vent stack, sparge gas used to regenerate glycol, and blanket gas used to maintain pressure in low pressure vessels)" to "instrument gas, and gas used to maintain pilot lights " Per industry comment, we changed "on the facility" to "on the lease."	You may classify and report gas used to operate equipment on the facility (such as gas used to power engines, gas used as pilot lights, instrument gas, purge gas used to prevent oxygen from entering the flare or vent stack, sparge gas used to regenerate glycol, and blanket gas used to maintain pressure in low pressure vessels) as lease use gas.	You may classify and report gas used to operate equipment on the lease, such as gas used to power engines, instrument gas, and gas used to maintain pilot lights, as lease use gas.
§ 250.1163(b)(3)—Per industry comment, we added language to clarify that this only applies to facilities that are required to have meters.	You must report the amount of gas flared and vented at each facility on a lease or unit basis. Gas flared and vented from multiple facilities on a single lease or unit must be reported separately.	If flare/vent meters are required at one or more of your facilities, you must report the amount of gas flared and vented at each of those facilities separately from those facilities that do not require meters and separately from other facilities with meters.
§ 250.1163(b)(4)—Per industry comment, added a new paragraph to clarify that if a facility is not required to have meters, the operator may report the amounts of gas flared or vented on a lease or unit basis. This reduces the reporting burden on industry.	No language proposed	Added new paragraph: (4) If flare/vent meters are not required at your facility: (i) You may report the gas flared and vented on a lease or unit basis. Gas flared and vented from multiple facilities on a single lease or unit may be reported together. (ii) If you choose to install meters, you may report the gas volume flared and vented according to the method specified in paragraph (b)(3) of this section.
§ 250.1163(c)—Restructured section. Split the introductory paragraph into subparagraphs and renumbered the section to conform. Removed reference to part 212, clarifying that the retention period for these records is 6 years, as specified in 30 U.S.C. 1713. The MMS promulgated regulations under this law at 30 CFR part 212, but specific reference to part 212 is not necessary here. Revised paragraph (2) to make consistent with language in § 250.1163(d)(1)(ii).	You must prepare and maintain records detailing gas flaring, gas venting, and liquid hydrocarbon burning for each facility. You must maintain these records for the period specified in part 212 of this title. You must keep these records on the facility for 2 years and have them available for inspection by MMS representatives. After 2 years, you must maintain the records, allow MMS representatives to inspect the records upon request, and provide copies to the Regional Supervisor upon request, but you are not required to keep them on the facility. The records must include, at a minimum: (1 O='xl') Daily volumes of gas flared, gas vented, and liquid hydrocarbons burned;. (2) Number of hours of gas flaring, gas venting, and liquid hydrocarbon burning, on a daily basis; (3) A list of the wells contributing to gas flaring, gas venting, and liquid hydrocarbon burning, along with gas-oil ratio data; (4) Reasons for gas flaring, gas venting, and liquid hydrocarbon burning; and (5) Documentation of all required approvals.	You must prepare and maintain records detailing gas flaring, gas venting, and liquid hydrocarbon burning for each facility for 6 years. (1) You must maintain these records on the facility for at least the first 2 years and have them available for inspection by MMS representatives. (2) After 2 years, you must maintain the records, allow MMS representatives to inspect the records upon request and provide copies to the Regional Supervisor upon request, but are not required to keep them on the facility. (3) The records must include, at a minimum: (i) Daily volumes of gas flared, gas vented, and liquid hydrocarbons burned; (ii) Number of hours of gas flaring, gas venting, and liquid hydrocarbon burning, on a daily and monthly cumulative basis; (iii) A list of the wells contributing to gas flaring, gas venting, and liquid hydrocarbon burning, along with gas-oil ratio data; (iv) Reasons for gas flaring, gas venting, and liquid hydrocarbon burning; and (v) Documentation of all required approvals.
§ 250.1163(c)(3)(ii)—Renumbered from § 250.1163(c)(2). Added that the records must include the number of hours of gas flaring, gas venting, and liquid hydrocarbon burning on a monthly cumulative basis. This number is normally recorded by operators. This specifies that operators are required to add up the monthly cumulative on the field records because inspectors need this to verify that the operators are in compliance with §§ 250.1160(a)(6)(iii) and (a)(7)(iii).	Number of hours of gas flaring, gas venting, and liquid hydrocarbon burning, on a daily basis;	Number of hours of gas flaring, gas venting, and liquid hydrocarbon burning, on a daily and monthly cumulative basis;

TABLE 3—CHANGES FROM THE PROPOSED RULE TO THIS FINAL RULE—Continued

Citation—description, or reason for the change	Proposed rule language	Final rule language
§ 250.1163(d)—Removed citations §§ 212.50 and 212.51. Restructured the section, to improve clarity. Retained the requirement to keep meter recordings for 6 years. Also added requirement for maintaining calibration and maintenance records.	If your facility is required to have flare/vent meters, you must maintain the meter recordings for the period specified in §§ 212.50 and 212.51 of this title. You must keep these recordings on the facility for 2 years and have them available for inspection by MMS representatives. After 2 years, you must maintain the recordings, allow MMS representatives to inspect the recordings upon request, and provide copies to the Regional Supervisor upon request, but are not required to keep them on the facility. These recordings must include the begin times, end times, and volumes for all flaring and venting incidents.	If your facility is required to have flare/vent meters: (1) You must maintain the meter recordings for 6 years. (i) You must keep these recordings on the facility for 2 years and have them available for inspection by MMS representatives. (ii) After 2 years, you must maintain the recordings, allow MMS representatives to inspect the recordings upon request and provide copies to the Regional Supervisor upon request, but are not required to keep them on the facility. (iii) These recordings must include the begin times, end times, and volumes for all flaring and venting incidents. (2) You must maintain flare/vent meter calibration and maintenance records on the facility for 2 years.
§ 250.1163(e)—Deleted reference to § 250.140, because that section only applies to oral approvals.	If your flaring or venting of gas, or burning of liquid hydrocarbons, required written or oral approval, you must submit documentation to the Regional Supervisor summarizing the location, dates, number of hours, and volumes of gas flared, gas vented, and liquid hydrocarbons burned under the approval, as required under § 250.140.	If your flaring or venting of gas, or burning of liquid hydrocarbons, required written or oral approval, you must submit documentation to the Regional Supervisor summarizing the location, dates, number of hours, and volumes of gas flared, gas vented, and liquid hydrocarbons burned under the approval.
§ 250.1164(b)(1)—Per industry comment, we deleted this paragraph since air quality guidelines are governed by Subpart C (Pollution Prevention and Control).	You may not emit more than 15 lbs of SO_2 per hour per mile from shore, without approval from the Regional Supervisor.	Deleted paragraph and renumbered subsequent paragraphs.
§ 250.1164(b)(2)—Added a reference to § 250.303 to clarify the authority for requesting additional air quality modeling analysis and the requirements for the analysis.	If the Regional Supervisor determines that flaring at a facility or group of facilities may significantly affect the air quality of an onshore area, the Regional Supervisor may require you to conduct an air quality modeling analysis to determine the potential effect of facility emissions. The Regional Supervisor may require monitoring and reporting, or may restrict or prohibit flaring, under §§ 250.303 and 250.304.	If the Regional Supervisor determines that flaring at a facility or group of facilities may significantly affect the air quality of an onshore area, the Regional Supervisor may require you to conduct an air quality modeling analysis, under § 250.303, to determine the potential effect of facility emissions. The Regional Supervisor may require monitoring and reporting, or may restrict or prohibit flaring, under §§ 250.303 and 250.304.
§ 250.1164(c)—Deleted first sentence in introductory paragraph regarding reporting flared and vented gas containing H_2S, because the reporting requirement is covered in paragraph (b) of this section.	You must report flared and vented gas containing H_2S as required under § 250.1163. In addition, the Regional Supervisor may require you to submit monthly reports of flared and vented gas containing H_2S.	The Regional Supervisor may require you to submit monthly reports of flared and vented gas containing H_2S.
§ 250.1165(b)—Removed the reference to supporting data (structure map and well log section) and cited § 250.1167 for the required supporting information for Form MMS–127.	Before initiating enhanced recovery operations, you must submit a proposed plan to the Regional Supervisor and receive approval for pressure maintenance, secondary or tertiary recovery, cycling, and similar recovery operations intended to increase the ultimate recovery of oil and gas from a reservoir. The proposed plan must include, for each project reservoir, a brief geologic and engineering overview, structure map, well log section, Form MMS–127, and any additional information required by the Regional Supervisor.	Before initiating enhanced recovery operations, you must submit a proposed plan to the Regional Supervisor and receive approval for pressure maintenance, secondary or tertiary recovery, cycling, and similar recovery operations intended to increase the ultimate recovery of oil and gas from a reservoir. The proposed plan must include, for each project reservoir, a geologic and engineering overview, Form MMS–127 and supporting data as required in § 250.1167, and any additional information required by the Regional Supervisor.
§ 250.1165(c)—Changed citation from § 216.53 to § 210.102 to conform with changes made in the Minerals Revenue Management regulations.	You must report to Minerals Revenue Management the volumes of oil, gas, or other substances injected, produced, or produced for a second time under § 216.53 of this title.	You must report to Minerals Revenue Management the volumes of oil, gas, or other substances injected, produced, or produced for a second time under § 210.102 of this title.

TABLE 3—CHANGES FROM THE PROPOSED RULE TO THIS FINAL RULE—Continued

Citation—description, or reason for the change	Proposed rule language	Final rule language
§ 250.1166(a)—Revised wording from "a greater ultimate recovery of oil and gas" to "maximize ultimate recovery of oil and gas." The new wording is consistent with terminology used in the rest of the rule.	For any development in the Alaska OCS Region, you must submit an annual reservoir management report to the Regional Supervisor. The report must contain information detailing the activities performed during the previous year and planned for the upcoming year that will provide for: (1) the prevention of waste; ..... (2) the protection of correlative rights; and ..... (3) a greater ultimate recovery of oil and gas.	For any development in the Alaska OCS Region, you must submit an annual reservoir management report to the Regional Supervisor. The report must contain information detailing the activities performed during the previous year and planned for the upcoming year that will: (1) provide for the prevention of waste; (2) provide for the protection of correlative rights; and (3) maximize ultimate recovery of oil and gas.
§ 250.1167—Revised introductory paragraph to clarify that columns 1 and 2 are for forms and columns 3 through 6 are for approvals.	You must submit the supporting information listed in the following table with the forms and for the approvals required under this subpart:.	You must submit the supporting information listed in the following table with the forms identified in columns 1 and 2 and for the approvals required under this subpart identified in columns 3 through 6:
§ 250.1167(a)(3) and(4) (table)—Changed the submittal requirement for net sand isopach with total net sand penetrated for each well, identified at the penetration point, and net hydrocarbon isopach with net feet of pay for each well, identified at the penetration point, for Form SRI MMS–127 from Required to Additional items the Regional Supervisor may request.	Required	Additional items the Regional Supervisor may request.
§ 250.1167(c)(2) (table)—Added that the Regional Supervisor may request the structural cross-sections for production within 500-ft of a lease or unit line.	Not required	Additional items the Regional Supervisor may request.
§ 250.1167(e)(5) (table)—Revised wording, from "will not harm ultimate recovery" to "will maximize ultimate recovery." This change is consistent with terminology used throughout the rest of the rule.	Explanation of why the proposed completion scenario will not harm ultimate recovery.	Explanation of why the proposed completion scenario will maximize ultimate recovery.

Final Rule Organization

The final rule completely restructures subpart K. The final rule is divided into shorter, easier-to-read sections, that focus on only one topic. For example, in the current subpart K regulation, the requirements regarding burning liquid hydrocarbons, as well as those governing flaring or venting natural gas, were all together in one section. In the final rule, these same requirements are in five sections, making it easier for an operator to find the information that applies to a particular situation. The numbering for subpart K starts at § 250.1150 instead of § 250.1100 to accommodate other planned rulemaking. The final rule structure is shown in the following table:

Current regulations	Final rule
§ 250.1100 Definitions for production rates	§ 250.105 Definitions.
§ 250.105 Definitions	
§ 250.1101 General requirements and classification of reservoirs	§ 250.1150 What are the general reservoir production requirements?
	§ 250.1154 How do I determine if my reservoir is sensitive?
	§ 250.1155 What information must I submit for sensitive reservoirs?
	§ 250.1156 What steps must I take to receive approval to produce within 500 feet of a unit or lease line?
	§ 250.1157 How do I receive approval to produce gas-cap gas from an oil reservoir with an associated gas cap?
§ 250.1102 Oil and gas production rates	Requirements for production rates are largely eliminated. Portions retained were combined with new information.
	§ 250.1159 May the Regional Supervisor limit my well or reservoir production rates?
§ 250.1103 Well production testing	§ 250.1151 How often must I conduct well production tests?
	§ 250.1152 How do I conduct well tests?
§ 250.1104 Bottomhole pressure survey	§ 250.1153 When must I conduct a static bottomhole pressure survey?
§ 250.1105 Flaring or venting of gas and burning liquid hydrocarbons	§ 250.1160 When may I flare or vent gas?
	§ 250.1161 When may I flare or vent gas for extended periods of time?
	§ 250.1162 When may I burn produced liquid hydrocarbons?
	§ 250.1163 How must I measure gas flaring or venting volumes and liquid hydrocarbon burning volumes and what records must I maintain?

Current regulations	Final rule
	§ 250.1164 What are the requirements for flaring or venting gas containing H_2S?
§ 250.1106 Downhole commingling	§ 250.1158 How do I receive approval to downhole commingle hydrocarbons?
§ 250.1107 Enhanced oil and gas recovery operations	§ 250.1165 What must I do for enhanced recovery operations?
New	§ 250.1159 May the Regional Supervisor limit my well or reservoir production rates?
	§ 250.1166 What additional reporting is required for developments in the Alaska OCS Region?
	§ 250.1167 What information must I submit with forms and for approvals?

Procedural Matters

Regulatory Planning and Review (Executive Order (E.O.) 12866)

The Office of Management and Budget (OMB) has designated this rule significant for OMB review under Executive Order 12866.

(1) The final rule will not have an annual effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. A cost-benefit and economic analysis is not required.

This final rule revises the requirements for oil and gas production. The changes in the rule are not significant enough to have an impact on the economy or an economic sector, productivity, jobs, the environment, or other units of government. Some of the previous requirements will be relaxed. For example, limits on production rates were eliminated in most cases. This will allow the operators to produce the oil and gas at the rates that they determine are best, and will not have a significant effect on any sector of the economy.

(2) The final rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency because MMS is the only Federal agency directly involved in setting production requirements for the offshore oil and natural gas industry.

(3) This final rule will not alter the budgetary effects of entitlements, grants, user fees or loan programs or the rights or obligations of their recipients.

(4) This final rule will raise novel legal or policy issues.

Regulatory Flexibility Act

The Department of the Interior certifies that this final rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

The changes in this rule will affect lessees and operators of leases in the OCS. This includes about 130 active Federal oil and gas lessees. Small lessees that operate under this rule fall under the Small Business Administration's (SBA) North American Industry Classification System (NAICS) codes 211111, Crude Petroleum and Natural Gas Extraction, and 213111, Drilling Oil and Gas Wells. For these NAICS code classifications, a small company is one with fewer than 500 employees. Based on these criteria, an estimated 70 percent of these companies are considered small. This final rule, therefore, will affect a substantial number of small entities, but the changes in the rule will not have a significant economic effect on a these entities.

The only new requirement that will impose a cost to operators is a requirement to install flaring/venting meters on all facilities that process more than 2,000 bopd. The GAO report on flaring and venting natural gas, released in July 2004, recommended that MMS require these meters to improve oversight. The MMS agrees with this recommendation. The MMS regulations allow flaring and venting in very limited circumstances. These meters will help MMS:

- Verify the amounts of natural gas that operators flare or vent into the environment;
- Prevent waste of resources;
- Collect the proper royalties on avoidably flared or vented gas;
- Determine if an operator is violating MMS regulations; and
- Assess the impacts on the environment.

In determining the criteria for which facilities must install the meters, MMS considered the cost of the meters and the amount of production needed to justify the cost. To ensure that the requirement to install flare/vent meters will not produce an undue burden on small companies, it is limited to those facilities that process more than an average of 2,000 bopd.

In the proposed rule, MMS estimated that 34 companies will have to install meters on 112 facilities at an average cost of $77,000 per facility, with a total cost to industry of $8,624,000 (112 × $77,000 = $8,624,000). Of those 34 companies, nine companies are considered small entities, based on the NAICS. These nine companies represent only 7 percent of the 130 operators in the OCS. We estimate that seven of these nine companies will need to install meters on one facility each; one company will need to install meters on two facilities; and one company will need to install meters on three facilities. This represents an average cost of $102,667 for each of the small companies (12 facilities × $77,000/9 companies). For the remaining companies, the average cost to install meters will be $308,000 per company (100 facilities × $77,000/25 companies). This does not represent an unfair burden to small companies because the cost of these meters is small in comparison to the revenues generated by the amount of oil processed by those facilities.

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 actions of MMS, call 1–888–734–3247. You may comment to the Small Business Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the SBA will be investigated for appropriate action.

Small Business Regulatory Enforcement Fairness Act

The final rule is not a major rule under 5 U.S.C. 804(2) of the Small Business Regulatory Enforcement Fairness Act. This final rule:

a. Will not have an annual effect on the economy of $100 million or more.

This final rule revises the requirements for oil and gas production. Most of the new requirements are paperwork requirements, and will not add significant time to development and production processes. One new requirement will add new costs for some operators. Operators will be required to install flare/vent meters on any facility that processes more than an average of 2,000 bopd. The MMS estimates that 34 companies will have to install meters on 112 facilities at an average cost of $77,000 per facility, with a total cost to industry of $8,624,000 (112 × $77,000 = $8,624,000).

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

The only change to this rule that has a cost associated with it is a new requirement to install meters on facilities that process more than an average of 2,000 bopd. As discussed previously, this requirement will not significantly increase the cost of doing business offshore and will not cause an increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This final rule will eliminate the requirement for operators to set limits on production rates, allowing the operators to determine the best rate to produce their reservoirs. There are clearer limits on burning, flaring, and venting, which will encourage conservation of our natural resources.

Unfunded Mandates Reform Act

This final rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The final rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings Implication Assessment (E.O. 12630)

Under the criteria in E.O. 12630, this final rule does not have significant takings implications. The final rule is not a governmental action capable of interference with constitutionally protected property rights. A Takings Implication Assessment is not required.

Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this final rule does not have federalism implications. This final rule will not substantially and directly affect the relationship between the Federal and State governments. To the extent that State and local governments have a role in OCS activities, this final rule will not affect that role. A Federalism Assessment is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175)

Under the criteria in E.O. 13175, we have evaluated this final rule and determined that it has no potential effects on federally recognized Indian tribes. There are no Indian or tribal lands in the OCS.

Paperwork Reduction Act (PRA)

This rulemaking is a total rewrite of regulations under 30 CFR Part 250, Subpart K, Oil and Gas Production Rates. The rule changes the information collection (IC) burden already approved for current subpart K regulations; therefore, a submission was made to OMB under 44 U.S.C. 3501 *et seq.* The OMB approved the collection of information under OMB Control Number 1010–0041, expiration date 3/31/2013, for a total of 43,396 burden hours and $9,234,392 non-hour cost burdens.

The title of the collection of information for the rule is *30 CFR Part 250, Subpart K, Oil and Gas Production Requirements.* Potential respondents comprise Federal oil and gas and sulphur lessees. Responses to this collection are mandatory or are required to obtain or retain a benefit. The frequency of response is on occasion, monthly, semi-annually, annually, and as a result of situations encountered depending upon the requirement. The information collection does not include questions of a sensitive nature. The MMS will protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), and 30 CFR 250.197, *Data and information to be made available to the public or for limited inspection,* and 30 CFR part 252, *OCS Oil and Gas Information Program.* Proprietary information concerning geological and geophysical data will be protected according to 43 U.S.C. 1352.

The information collected under subpart K is used in our efforts to conserve natural resources, prevent waste, and protect correlative rights, including the Government's royalty interest. Specifically, MMS uses the information to:

- Evaluate requests to burn liquid hydrocarbons and vent and flare gas to ensure that these requests are appropriate;
- Determine if a maximum production or efficient rate is required; and,
- Review applications for downhole commingling to ensure that action maximizes ultimate recovery.

The IC burdens for these regulations include several changes from the burdens published in the preamble to the proposed rule. The changes and reasons for making them are:

(1) On August 25, 2008 (73 FR 49943) a final rulemaking was published that increased the cost recovery fees required under § 250.125. These fees became effective on September 24, 2008, and the final rule includes these fees that affect subpart K.

(2) The OMB approval of the information collection burden (1010–0041) for the current subpart K regulations was due to expire before these final regulations became effective. As required by the Paperwork Reduction Act, to renew the OMB approval of 1010–0041, we consulted with several respondents and adjusted the burden estimates and number of responses accordingly. The burden estimates for the final rule reflect these updates.

(3) Based on a public comment, we removed the requirements published in proposed § 250.1164(b)(1) to request Regional Supervisor approval for emitting more than 15 pounds of SO_2, and § 250.1164(b)(2), submit to the Regional Supervisor air quality modeling analysis. The commenter stated that 30 CFR 250, subpart C, was sufficient to regulate pollution issues and MMS agreed.

(4) We also added two IC requirements and burdens to the following IC burden table for the final regulations.

(a) First, operators/lessees must provide notice to operator(s) of adjacent property(ies) of their request for MMS approval to produce within 500 feet of a unit or lease line or to commingle

hydrocarbons. Sections 250.1156(b) and 250.1158(b) allow the notified party(ies) to submit letters of acceptance or objection to MMS. This provision was in the proposed rule, but was inadvertently omitted from the IC table in the proposed rule.

(b) Second, is a new paragraph (1) under § 250.1163(a) that requires a notice to MMS when a facility begins to process more than an average of 2,000 BOPD per month. This change was made in response to a commenter's concern that the current Oil and Gas Operations Report (OGOR)–B form does not allow for multiple facility submissions.

30 CFR part 250 subpart K	Reporting & recordkeeping requirement	Non-hour cost burdens		
		Hour burden	Average number of annual responses	Annual burden hours
WELL TESTS/SURVEYS and CLASSIFYING RESERVOIRS				
1151(a)(1), (c); 1167 ..	Conduct well production test; submit Form MMS–126 (Well Potential Test Report) and supporting information (within 15 days after end of test period).	3	1,325 forms	3,975
1151(a)(2), (c); 1167 ..	Conduct well production test; submit Form MMS–128 (Semiannual Well Test Report) and supporting information (within 45 days after end of calendar half-year).	0.1 to 3*	13,000 GOM forms 600 POCS forms.	3,100
1151(b)	Request extension of time to submit results of semi-annual well test.	0.5	37 requests	19
1152(b), (c)	Request approval to conduct well testing using alternative procedures.	0.5	37 requests	19
1152(d)	Provide advance notice of time and date of well tests.	0.5	10 notices	5
1153	Conduct static bottomhole pressure survey; submit Form MMS–140 (Bottomhole Pressure Survey Report) (within 60 days after survey).	14	1,270 surveys	17,780
1153(d)	Submit a letter, along with Form MMS–140, to request a departure from requirement to run a static bottomhole survey.	1	120 survey departures.	120
1154; 1167	Request approval, along with supporting information, to reclassify reservoir.	6	20 requests	120
1155; 1165(b); 1166(c); 1167.	Submit Form MMS–127 (Sensitive Reservoir Information Report) and supporting information (within 45 days after certain events or at least annually).	2.2	2,189 forms	4,816
Subtotal			18,608 responses	29,954 hours
APPROVALS PRIOR TO PRODUCTION				
1156; 1167	Request approval to produce within 500 feet of a unit or lease line; submit supporting information; pay service fee and include pay.gov payment confirmation with request; notify adjacent operators and provide MMS proof of notice date.	5	33 requests	165
		$3,608 × 33 requests = $119,064		
1156(b); 1158(b)	Notify adjacent operators submit letters of acceptance or objection to MMS within 30 days after notice.	.5	33 letters	17 (rounded)
1157; 1167	Request approval to produce gas-cap gas in an oil reservoir with an associated gas cap, or to continue producing an oil well showing characteristics of a gas well with an associated gas cap; submit supporting information; pay service fee and include pay.gov payment confirmation with request.	12	51 requests	612
		$4,592 × 51 requests = $234,192		

30 CFR part 250 subpart K	Reporting & recordkeeping requirement	Non-hour cost burdens		
		Hour burden	Average number of annual responses	Annual burden hours
1158; 1167	Request approval to downhole commingle hydrocarbons; submit supporting information; pay service fee and include pay.gov payment confirmation with request; notify operators and provide proof of notice date.	6	48 applications	288
		$5,357 × 48 applications = $257,136		
			165 responses	1,082 hours
Subtotal			$610,392 non-hour costs	
FLARING, VENTING, and BURNING HYDROCARBONS				
1160; 1161; 1163(e)	Request approval to flare or vent natural gas or exceed specified volumes; submit documentation; report flare/vent information due to blow down of transportation pipelines within 72 hours after incident.	0.5	1,007 requests/ reports.	504
1162; 1163(e)	Request approval to burn produced liquid hydrocarbons; submit documentation	0.5	60 requests/ reports.	30
1163(a)	One-time initial purchase and installation of gas meters to measure and record the amount of gas flared or vented. This is a non-hour cost burden required to comply with revised regulations with relatively small or no burden in subsequent years.	112 meters × $77,000 ea = $8,624,000		
1163(a)(1)	Notify MMS when facility begins to process more than an average of 2,000 bopd per month.	0.833	112 notices	93 (rounded)
1163(b); 1164(c)	Report to MRM hydrocarbons produced, including measured gas flared/vented and liquid hydrocarbon burned—burden covered under 1010–0139.			0
1163(c), (d)	Maintain records for 6 years detailing gas flaring/venting, liquid hydrocarbon burning; and flare/vent meter recordings; make available for inspection or provide copies upon request.	13	869 flare/vent platforms.	11,297
		0.5	60 liquid hydrocarbons.	30
1164(c)	Submit monthly reports of flared or vented gas containing H_2S.	2	3 operators × 12 mos. = 36.	72
1160(b); 1164(b)(1), (2).	H_2S Contingency, Exploration, or Development and Production Plans and, Development Operations Coordination Documents—burdens covered under 1010–0141 and 1010–0151. Monitor air quality and report—burdens covered under 1010–0057.			0
			2,084 responses	12,026 hours
Subtotal			$8,624,000 non-hour costs	
OTHER REQUIREMENTS				
1165	Submit proposed plan and supporting information for enhanced recovery operations; including Form MMS–127.	12	14 plans	168
1165(c)	Submit periodic reports of volumes of oil, gas, or other substances injected, produced, or produced for a second time—burden covered under OMB approval 1010–0139.			0
1166	Alaska Region only: submit annual reservoir management report and supporting information, including Form MMS–127.	1	1 (req'd by State, MMS gets copy).	1
		100	1 new development not State lands.	100

30 CFR part 250 subpart K	Reporting & recordkeeping requirement	Non-hour cost burdens		
		Hour burden	Average number of annual responses	Annual burden hours
1150–1167	General departure or alternative compliance requests not specifically covered elsewhere in subpart K.	20 1	3 annual revisions 5 submissions	60 5
Subtotal			24 responses	334 hours
			20,881 responses	43,396 hours
TOTAL BURDEN			$9,234,392 non-hour cost burdens	

* Reporting burden for this form is estimated to average 0.1 to 3 hours per form depending on the number of well tests reported, including the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the form.

An agency may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public may comment, at any time, on the accuracy of the IC burden in this rule and may submit any comments to the Department of the Interior; Minerals Management Service; Attention: Regulations and Standards Branch; Mail Stop 5438; 381 Elden Street; Herndon, Virginia 20170–4817.

National Environmental Policy Act of 1969

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it falls within the MMS categorical exclusion covering the "[i]ssuance and modification of regulations, Orders, Standards, Notices to Lessees and Operators. Guidelines and field rules for which the impacts are limited to administrative, economic, or technological effects and the environmental impacts are minimal." This categorical exclusion is documented in 516 Departmental Manual 15.4(C)(1). We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under the National Environmental Policy Act.

Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554, app. C § 515, 114 Stat. 2763, 2763A–153–154).

Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

List of Subjects in 30 CFR Part 250

Continental shelf, Environmental protection, Oil and gas exploration, Public lands—mineral resources, reporting and recordkeeping requirements.

Dated: December 23, 2009.

Ned Farquhar,

Acting Assistant Secretary—Land and Minerals Management.

■ For the reasons stated in the preamble, Minerals Management Service (MMS) amends 30 CFR part 250 as follows:

PART 250—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for part 250 continues to read as follows:

Authority: 31 U.S.C. 9701, 43 U.S.C. 1334.

■ 2. Amend § 250.105 by revising the definition of *Sensitive reservoir* and adding in alphabetical order definitions for *Flaring* and *Venting* to read as follows:

§ 250.105 Definitions.

* * * * *

Flaring means the burning of natural gas as it is released into the atmosphere.

* * * * *

Sensitive reservoir means a reservoir in which the production rate will affect ultimate recovery.

* * * * *

Venting means the release of gas into the atmosphere without igniting it. This includes gas that is released underwater and bubbles to the atmosphere.

* * * * *

■ 3. In § 250.125, revise paragraphs (a)(27) through (29) to read as follows:

§ 250.125 Service fees.

(a) * * *

SERVICE FEE TABLE

Service—processing of the following:	Fee amount	30 CFR citation
.		
* * * * * *		*
(27) 500 Feet From Lease/Unit Line Production Request	3,608	§ 250.1156(a).
(28) Gas Cap Production Request	4,592	§ 250.1157.
(29) Downhole Commingling Request	5,357	§ 250.1158(a).
* * * * * *		*

■ 4. In § 250.199, paragraph (e)(10) is revised to read as follows:

§ 250.199 Paperwork Reduction Act statements—information collection.

(e) * * *

* * * * *

30 CFR subpart, title and/or MMS Form (OMB Control No.)	Reasons for collecting information and how used
* * * * * * *	
(10) Subpart K, Oil and Gas Production Rates (1010–0041), including Forms MMS–126, Well Potential Test Report; MMS–127, Sensitive Reservoir Information Report; MMS–128, Semiannual Well Test Report; MMS–140 Bottomhole Pressure Survey Report.	To inform MMS of production rates for hydrocarbons produced on the OCS. To ensure economic maximization of ultimate hydrocarbon recovery.
* * * * * * *	

§ 250.490 [Amended]

■ 5. In § 250.490, paragraph (o)(3), the citation "§ 250.1105" is revised to read "§ 250.1164".

■ 6. Revise subpart K to read as follows:

Subpart K—Oil and Gas Production Requirements

General

Sec.

General

§ 250.1150 What are the general reservoir production requirements?

You must produce wells and reservoirs at rates that provide for economic development while maximizing ultimate recovery and without adversely affecting correlative rights.

Well Tests and Surveys

§ 250.1151 How often must I conduct well production tests?

(a) You must conduct well production tests as shown in the following table:

You must conduct:	And you must submit to the Regional Supervisor:
(1) A well-flow potential test on all new, recompleted, or reworked well completions within 30 days of the date of first continuous production.	Form MMS–126, Well Potential Test Report, along with the supporting data as listed in the table in § 250.1167, within 15 days after the end of the test period.
(2) At least one well test during a calendar half-year for each producing completion.	Results on Form MMS–128, Semiannual Well Test Report, of the most recent well test obtained. This must be submitted within 45 days after the end of the calendar half-year.

(b) You may request an extension from the Regional Supervisor if you cannot submit the results of a semiannual well test within the specified time.

(c) You must submit to the Regional Supervisor an original and two copies of the appropriate form required by paragraph (a) of this section; one of the copies of the form must be a public information copy in accordance with §§ 250.186 and 250.197, and marked "Public Information." You must submit two copies of the supporting information as listed in the table in § 250.1167 with form MMS–126.

§ 250.1152 How do I conduct well tests?

(a) When you conduct well tests you must:

(1) Recover fluid from the well completion equivalent to the amount of fluid introduced into the formation during completion, recompletion, reworking, or treatment operations before you start a well test;

(2) Produce the well completion under stabilized rate conditions for at least 6 consecutive hours before beginning the test period;

(3) Conduct the test for at least 4 consecutive hours;

(4) Adjust measured gas volumes to the standard conditions of 14.73 pounds per square inch absolute (psia) and 60° F for all tests; and

(5) Use measured specific gravity values to calculate gas volumes.

(b) You may request approval from the Regional Supervisor to conduct a well test using alternative procedures if you can demonstrate test reliability under those procedures.

(c) The Regional Supervisor may also require you to conduct the following tests and complete them within a specified time period:

(1) A retest or a prolonged test of a well completion if it is determined to be necessary for the proper establishment of a Maximum Production Rate (MPR) or a Maximum Efficient Rate (MER); and

(2) A multipoint back-pressure test to determine the theoretical open-flow potential of a gas well.

(d) An MMS representative may witness any well test. Upon request, you must provide advance notice to the Regional Supervisor of the times and dates of well tests.

§ 250.1153 When must I conduct a static bottomhole pressure survey?

(a) You must conduct a static bottomhole pressure survey under the following conditions:

If you have . . .	Then you must conduct . . .
(1) A new producing reservoir	A static bottomhole pressure survey within 90 days after the date of first continuous production.
(2) A reservoir with three or more producing completions	Annual static bottomhole pressure surveys in a sufficient number of key wells to establish an average reservoir pressure. The Regional Supervisor may require that bottomhole pressure surveys be performed on specific wells.

(b) Your bottomhole pressure survey must meet the following requirements:

(1) You must shut-in the well for a minimum period of 4 hours to ensure stabilized conditions; and

(2) The bottomhole pressure survey must consist of a pressure measurement at mid-perforation, and pressure measurements and gradient information for at least four gradient stops coming out of the hole.

(c) You must submit to the Regional Supervisor the results of all static bottomhole pressure surveys on Form MMS–140, Bottomhole Pressure Survey Report, within 60 days after the date of the survey.

(d) The Regional Supervisor may grant a departure from the requirement to run a static bottomhole pressure survey. To request a departure, you must submit a justification, along with Form MMS–140, Bottomhole Pressure Survey Report, showing a calculated bottomhole pressure or any measured data.

Classifying Reservoirs

§ 250.1154 How do I determine if my reservoir is sensitive?

(a) You must determine whether each reservoir is sensitive. You must classify the reservoir as sensitive if:

(1) Under initial conditions it is an oil reservoir with an associated gas cap;

(2) At any time there are near-critical fluids; or

(3) The reservoir is undergoing enhanced recovery.

(b) For the purposes of this subpart, near-critical fluids are:

(1) Those fluids that occur in high temperature, high-pressure reservoirs where it is not possible to define the liquid-gas contact; or

(2) Fluids in reservoirs that are near bubble point or dew point conditions.

(c) The Regional Supervisor may reclassify a reservoir when available information warrants reclassification.

(d) If available information indicates that a reservoir previously classified as non-sensitive is now sensitive, you must submit a request to the Regional Supervisor to reclassify the reservoir. You must include supporting information, as listed in the table in § 250.1167, with your request.

(e) If information indicates that a reservoir previously classified as sensitive is now non-sensitive, you may submit a request to the Regional Supervisor to reclassify the reservoir. You must include supporting information, as listed in the table in § 250.1167, with your request.

§ 250.1155 What information must I submit for sensitive reservoirs?

You must submit to the Regional Supervisor an original and two copies of Form MMS–127; one of the copies must be a public information copy in accordance with §§ 250.186 and 250.197, and marked "Public Information." You must also submit two copies of the supporting information, as listed in the table in § 250.1167. You must submit this information:

(a) Within 45 days after beginning production from the reservoir or discovering that it is sensitive;

(b) At least once during the calendar year, but you do not need to resubmit unrevised structure maps (§ 250.1167(a)(2)) or previously submitted well logs (§ 250.1167(c)(1));

(c) Within 45 days after you revise reservoir parameters; and

(d) Within 45 days after the Regional Supervisor classifies the reservoir as sensitive under § 250.1154(c).

Approvals Prior to Production

§ 250.1156 What steps must I take to receive approval to produce within 500 feet of a unit or lease line?

(a) You must obtain approval from the Regional Supervisor before you start producing from a reservoir within a well that has any portion of the completed interval less than 500 feet from a unit or lease line. Submit to MMS the service fee listed in § 250.125, according to the instructions in § 250.126, and the supporting information, as listed in the table in § 250.1167, with your request. The Regional Supervisor will determine whether approval of your request will maximize ultimate recovery, avoid the waste of natural resources, or protect correlative rights. You do not need to obtain approval if the adjacent leases or units have the same unit, lease (record title and operating rights), and royalty interests as the lease or unit you plan to produce. You do not need to obtain approval if the adjacent block is unleased.

(b) You must notify the operator(s) of adjacent property(ies) that are within 500 feet of the completion, if the adjacent acreage is a leased block in the Federal OCS. You must provide the Regional Supervisor proof of the date of the notification. The operators of the adjacent properties have 30 days after receiving the notification to provide the Regional Supervisor letters of acceptance or objection. If an adjacent operator does not respond within 30 days, the Regional Supervisor will presume there are no objections and proceed with a decision. The notification must include:

(1) The well name;

(2) The rectangular coordinates (x, y) of the location of the top and bottom of the completion or target completion referenced to the North American Datum 1983, and the subsea depths of the top and bottom of the completion or target completion;

(3) The distance from the completion or target completion to the unit or lease line at its nearest point; and

(4) A statement indicating whether or not it will be a high-capacity completion having a perforated or open hole interval greater than 150 feet measured depth.

§ 250.1157 How do I receive approval to produce gas-cap gas from an oil reservoir with an associated gas cap?

(a) You must request and receive approval from the Regional Supervisor:

(1) Before producing gas-cap gas from each completion in an oil reservoir that is known to have an associated gas cap.

(2) To continue production from a well if the oil reservoir is not initially known to have an associated gas cap, but the oil well begins to show characteristics of a gas well.

(b) For either request, you must submit the service fee listed in § 250.125, according to the instructions in § 250.126, and the supporting information, as listed in the table in § 250.1167, with your request.

(c) The Regional Supervisor will determine whether your request maximizes ultimate recovery.

§ 250.1158 How do I receive approval to downhole commingle hydrocarbons?

(a) Before you perforate a well, you must request and receive approval from the Regional Supervisor to commingle hydrocarbons produced from multiple reservoirs within a common wellbore. The Regional Supervisor will determine whether your request maximizes ultimate recovery. You must include the service fee listed in § 250.125, according to the instructions in § 250.126, and the supporting information, as listed in the table in § 250.1167, with your request.

(b) If one or more of the reservoirs proposed for commingling is a competitive reservoir, you must notify the operators of all leases that contain the reservoir that you intend to downhole commingle the reservoirs. Your request for approval of downhole commingling must include proof of the date of this notification. The notified operators have 30 days after notification to provide the Regional Supervisor with letters of acceptance or objection. If the notified operators do not respond within the specified period, the Regional Supervisor will assume the operators do not object and proceed with a decision.

Production Rates

§ 250.1159 May the Regional Supervisor limit my well or reservoir production rates?

(a) The Regional Supervisor may set a Maximum Production Rate (MPR) for a producing well completion, or set a Maximum Efficient Rate (MER) for a reservoir, or both, if the Regional Supervisor determines that an excessive production rate could harm ultimate recovery. An MPR or MER will be based on well tests and any limitations imposed by well and surface equipment, sand production, reservoir sensitivity, gas-oil and water-oil ratios, location of perforated intervals, and prudent operating practices.

(b) If the Regional Supervisor sets an MPR for a producing well completion and/or an MER for a reservoir, you may not exceed those rates except due to normal variations and fluctuations in production rates as set by the Regional Supervisor.

Flaring, Venting, and Burning Hydrocarbons

§ 250.1160 When may I flare or vent gas?

(a) You must request and receive approval from the Regional Supervisor to flare or vent natural gas at your facility, except in the following situations:

Condition	Additional requirements
(1) When the gas is lease use gas (produced natural gas which is used on or for the benefit of lease operations such as gas used to operate production facilities) or is used as an additive necessary to burn waste products, such as H_2S.	The volume of gas flared or vented may not exceed the amount necessary for its intended purpose. Burning waste products may require approval under other regulations.
(2) During the restart of a facility that was shut in because of weather conditions, such as a hurricane.	Flaring or venting may not exceed 48 cumulative hours without Regional Supervisor approval.
(3) During the blow down of transportation pipelines downstream of the royalty meter.	(i) You must report the location, time, flare/vent volume, and reason for flaring/venting to the Regional Supervisor in writing within 72 hours after the incident is over. (ii) Additional approval may be required under subparts H and J of this part.
(4) During the unloading or cleaning of a well, drill-stem testing, production testing, other well-evaluation testing, or the necessary blow down to perform these procedures.	You may not exceed 48 cumulative hours of flaring or venting per unloading or cleaning or testing operation on a single completion without Regional Supervisor approval.
(5) When properly working equipment yields flash gas (natural gas released from liquid hydrocarbons as a result of a decrease in pressure, an increase in temperature, or both) from storage vessels or other low-pressure production vessels, and you cannot economically recover this flash gas.	You may not flare or vent more than an average of 50 MCF per day during any calendar month without Regional Supervisor approval.
(6) When the equipment works properly but there is a temporary upset condition, such as a hydrate or paraffin plug.	(i) For oil-well gas and gas-well flash gas (natural gas released from condensate as a result of a decrease in pressure, an increase in temperature, or both), you may not exceed 48 continuous hours of flaring or venting without Regional Supervisor approval. (ii) For primary gas-well gas (natural gas from a gas well completion that is at or near its wellhead pressure; this does not include flash gas), you may not exceed 2 continuous hours of flaring or venting without Regional Supervisor approval. (iii) You may not exceed 144 cumulative hours of flaring or venting during a calendar month without Regional Supervisor approval.
(7) When equipment fails to work properly, during equipment maintenance and repair, or when you must relieve system pressures.	(i) For oil-well gas and gas-well flash gas, you may not exceed 48 continuous hours of flaring or venting without Regional Supervisor approval. (ii) For primary gas-well gas, you may not exceed 2 continuous hours of flaring or venting without Regional Supervisor approval. (iii) You may not exceed 144 cumulative hours of flaring or venting during a calendar month without Regional Supervisor approval. (iv) The continuous and cumulative hours allowed under this paragraph may be counted separately from the hours under paragraph (a)(6) of this section.

(b) Regardless of the requirements in paragraph (a) of this section, you must not flare or vent gas over the volume approved in your Development Operations Coordination Document (DOCD) or your Development and Production Plan (DPP).

(c) The Regional Supervisor may establish alternative approval procedures to cover situations when you cannot contact the MMS office, such as during non-office hours.

(d) The Regional Supervisor may specify a volume limit, or a shorter time limit than specified elsewhere in this part, in order to prevent air quality degradation or loss of reserves.

(e) If you flare or vent gas without the required approval, or if the Regional Supervisor determines that you were negligent or could have avoided flaring or venting the gas, the hydrocarbons will be considered avoidably lost or wasted. You must pay royalties on the loss or waste, according to part 202 of this title. You must value any gas or liquid hydrocarbons avoidably lost or wasted under the provisions of part 206 of this title.

(f) Fugitive emissions from valves, fittings, flanges, pressure relief valves or similar components do not require approval under this subpart unless specifically required by the Regional Supervisor.

§ 250.1161 When may I flare or vent gas for extended periods of time?

You must request and receive approval from the Regional Supervisor to flare or vent gas for an extended period of time. The Regional Supervisor will specify the approved period of time, which will not exceed 1 year. The Regional Supervisor may deny your request if it does not ensure the conservation of natural resources or is not consistent with national interests relating to development and production of minerals of the OCS. The Regional Supervisor may approve your request for one of the following reasons:

(a) You initiated an action which, when completed, will eliminate flaring and venting; or

(b) You submit to the Regional Supervisor an evaluation supported by engineering, geologic, and economic data indicating that the oil and gas produced from the well(s) will not economically support the facilities necessary to sell the gas or to use the gas on or for the benefit of the lease.

§ 250.1162 When may I burn produced liquid hydrocarbons?

(a) You must request and receive approval from the Regional Supervisor to burn any produced liquid hydrocarbons. The Regional Supervisor may allow you to burn liquid hydrocarbons if you demonstrate that transporting them to market or re-injecting them is not technically feasible or poses a significant risk of harm to offshore personnel or the environment.

(b) If you burn liquid hydrocarbons without the required approval, or if the Regional Supervisor determines that you were negligent or could have avoided burning liquid hydrocarbons, the hydrocarbons will be considered avoidably lost or wasted. You must pay royalties on the loss or waste, according to part 202 of this title. You must value any liquid hydrocarbons avoidably lost or wasted under the provisions of part 206 of this title.

§ 250.1163 How must I measure gas flaring or venting volumes and liquid hydrocarbon burning volumes, and what records must I maintain?

(a) If your facility processes more than an average of 2,000 bopd during May 2010, you must install flare/vent meters within 180 days after May 2010. If your facility processes more than an average of 2,000 bopd during a calendar month after May 2010, you must install flare/vent meters within 120 days after the end of the month in which the average amount of oil processed exceeds 2,000 bopd.

(1) You must notify the Regional Supervisor when your facility begins to process more than an average of 2,000 bopd in a calendar month;

(2) The flare/vent meters must measure all flared and vented gas within 5 percent accuracy;

(3) You must calibrate the meters regularly, in accordance with the manufacturer's recommendation, or at least once every year, whichever is shorter; and

(4) You must use and maintain the flare/vent meters for the life of the facility.

(b) You must report all hydrocarbons produced from a well completion, including all gas flared, gas vented, and liquid hydrocarbons burned, to Minerals Revenue Management on Form MMS–4054 (Oil and Gas Operations Report), in accordance with § 210.102 of this title.

(1) You must report the amount of gas flared and the amount of gas vented separately.

(2) You may classify and report gas used to operate equipment on the lease, such as gas used to power engines, instrument gas, and gas used to maintain pilot lights, as lease use gas.

(3) If flare/vent meters are required at one or more of your facilities, you must report the amount of gas flared and vented at each of those facilities separately from those facilities that do not require meters and separately from other facilities with meters.

(4) If flare/vent meters are not required at your facility:

(i) You may report the gas flared and vented on a lease or unit basis. Gas flared and vented from multiple facilities on a single lease or unit may be reported together.

(ii) If you choose to install meters, you may report the gas volume flared and vented according to the method specified in paragraph (b)(3) of this section.

(c) You must prepare and maintain records detailing gas flaring, gas venting, and liquid hydrocarbon burning for each facility for 6 years.

(1) You must maintain these records on the facility for at least the first 2 years and have them available for inspection by MMS representatives.

(2) After 2 years, you must maintain the records, allow MMS representatives to inspect the records upon request and provide copies to the Regional Supervisor upon request, but are not required to keep them on the facility.

(3) The records must include, at a minimum:

(i) Daily volumes of gas flared, gas vented, and liquid hydrocarbons burned;

(ii) Number of hours of gas flaring, gas venting, and liquid hydrocarbon burning, on a daily and monthly cumulative basis;

(iii) A list of the wells contributing to gas flaring, gas venting, and liquid hydrocarbon burning, along with gas-oil ratio data;

(iv) Reasons for gas flaring, gas venting, and liquid hydrocarbon burning; and

(v) Documentation of all required approvals.

(d) If your facility is required to have flare/vent meters:

(1) You must maintain the meter recordings for 6 years.

(i) You must keep these recordings on the facility for 2 years and have them available for inspection by MMS representatives.

(ii) After 2 years, you must maintain the recordings, allow MMS representatives to inspect the recordings upon request and provide copies to the Regional Supervisor upon request, but are not required to keep them on the facility.

(iii) These recordings must include the begin times, end times, and volumes for all flaring and venting incidents.

(2) You must maintain flare/vent meter calibration and maintenance records on the facility for 2 years.

(e) If your flaring or venting of gas, or burning of liquid hydrocarbons, required written or oral approval, you must submit documentation to the Regional Supervisor summarizing the location, dates, number of hours, and volumes of gas flared, gas vented, and liquid hydrocarbons burned under the approval.

§ 250.1164 What are the requirements for flaring or venting gas containing H_2S?

(a) You may not vent gas containing H_2S, except for minor releases during maintenance and repair activities that do not result in a 15-minute time-weighted average atmosphere concentration of H_2S of 20 ppm or higher anywhere on the platform.

(b) You may flare gas containing H_2S only if you meet the requirements of §§ 250.1160, 250.1161, 250.1163, and the following additional requirements:

(1) For safety or air pollution prevention purposes, the Regional Supervisor may further restrict the flaring of gas containing H_2S. The Regional Supervisor will use information provided in the lessee's H_2S Contingency Plan (§ 250.490(f)), Exploration Plan, DPP, DOCD, and associated documents to determine the need for restrictions; and

(2) If the Regional Supervisor determines that flaring at a facility or group of facilities may significantly affect the air quality of an onshore area, the Regional Supervisor may require you to conduct an air quality modeling analysis, under § 250.303, to determine the potential effect of facility emissions. The Regional Supervisor may require monitoring and reporting, or may restrict or prohibit flaring, under §§ 250.303 and 250.304.

(c) The Regional Supervisor may require you to submit monthly reports of flared and vented gas containing H_2S. Each report must contain, on a daily basis:

(1) The volume and duration of each flaring and venting occurrence;

(2) H_2S concentration in the flared or vented gas; and

(3) The calculated amount of SO_2 emitted.

Other Requirements

§ 250.1165 What must I do for enhanced recovery operations?

(a) You must promptly initiate enhanced oil and gas recovery operations for all reservoirs where these operations would result in an increase in ultimate recovery of oil or gas under sound engineering and economic principles.

(b) Before initiating enhanced recovery operations, you must submit a proposed plan to the Regional Supervisor and receive approval for pressure maintenance, secondary or tertiary recovery, cycling, and similar recovery operations intended to increase the ultimate recovery of oil and gas from a reservoir. The proposed plan must include, for each project reservoir, a geologic and engineering overview, Form MMS–127 and supporting data as required in § 250.1167, and any additional information required by the Regional Supervisor.

(c) You must report to Minerals Revenue Management the volumes of oil, gas, or other substances injected, produced, or produced for a second time under § 210.102 of this title.

§ 250.1166 What additional reporting is required for developments in the Alaska OCS Region?

(a) For any development in the Alaska OCS Region, you must submit an annual reservoir management report to the Regional Supervisor. The report must contain information detailing the activities performed during the previous year and planned for the upcoming year that will:

(1) Provide for the prevention of waste;

(2) Provide for the protection of correlative rights; and

(3) Maximize ultimate recovery of oil and gas.

(b) If your development is jointly regulated by MMS and the State of Alaska, MMS and the Alaska Oil and Gas Conservation Commission will jointly determine appropriate reporting requirements to minimize or eliminate duplicate reporting requirements.

(c) Every time you are required to submit Form MMS–127 under § 250.1155, you must request an MER for each producing sensitive reservoir in the Alaska OCS Region, unless otherwise instructed by the Regional Supervisor.

§ 250.1167 What information must I submit with forms and for approvals?

You must submit the supporting information listed in the following table with the forms identified in columns 1 and 2 and for the approvals required under this subpart identified in columns 3 through 6:

	WPT MMS–126 (2 copies)	SRI MMS–127 (2 copies)	Gas cap production	Downhole commingling	Reservoir reclassification	Production within 500-ft of a unit or lease line
(a) Maps:						
(1) Base map with surface, bottomhole, and completion locations with respect to the unit or lease line and the orientation of representative seismic lines or cross-sections	.....	.....	√	√	.....	√
(2) Structure maps with penetration point and subsea depth for each well penetrating the reservoirs, highlighting subject wells; reservoir boundaries; and original and current fluid levels	√	√	√	√	√	√
(3) Net sand isopach with total net sand penetrated for each well, identified at the penetration point	.....	*	√	√		
(4) Net hydrocarbon isopach with net feet of pay for each well, identified at the penetration point	.....	*	√	√		
(b) Seismic data:						
(1) Representative seismic lines, including strike and dip lines that confirm the structure; indicate polarity	.....	.....	√	√	.....	√
(2) Amplitude extraction of seismic horizon, if applicable	.....	.....	√	√	√	√
(c) Logs:						
(1) Well log sections with tops and bottoms of the reservoir(s) and proposed or existing perforations	√	√	√	√	√	√
(2) Structural cross-sections showing the subject well and nearby wells	.....	.....	√	√	√	*
(d) Engineering data:						

	WPT MMS–126 (2 copies)	SRI MMS–127 (2 copies)	Gas cap production	Downhole commingling	Reservoir reclassification	Production within 500-ft of a unit or lease line
(1) Estimated recoverable reserves for each well completion in the reservoir; total recoverable reserves for each reservoir; method of calculation; reservoir parameters used in volumetric and decline curve analysis	.....	√	†	†	.....	√
(2) Well schematics showing current and proposed conditions	.....	.....	√	√	.....	√
(3) The drive mechanism of each reservoir	.....	√	√	√	√	√
(4) Pressure data, by date, and whether they are estimated or measured	.....	.....	√	√	√	
(5) Production data and decline curve analysis indicative of the reservoir performance	.....	.....	√	√	√	
(6) Reservoir simulation with the reservoir parameters used, history matches, and prediction runs (include proposed development scenario)	.....	.....	*	*	*	*
(e) General information:						
(1) Detailed economic analysis	.....	.....	*	*		
(2) Reservoir name and whether or not it is competitive as defined under § 250.105	.....	√	√	√	√	√
(3) Operator name, lessee name(s), block, lease number, royalty rate, and unit number (if applicable) of all relevant leases	.....	.....	√	√	.....	√
(4) Geologic overview of project	.....	.....	√	√	√	√
(5) Explanation of why the proposed completion scenario will maximize ultimate recovery	.....	.....	√	√	.....	√
(6) List of all wells in subject reservoirs that have ever produced or been used for injection	.....	.....	√	√	√	√

√ Required.

† Each Gas Cap Production request and Downhole Commingling request must include the estimated recoverable reserves for (1) the case where your proposed production scenario is approved, and (2) the case where your proposed production scenario is denied.

* Additional items the Regional Supervisor may request.

Note: All maps must be at a standard scale and show lease and unit lines. The Regional Supervisor may waive submittal of some of the required data on a case-by-case basis.

(f) Depending on the type of approval requested, you must submit the appropriate payment of the service fee(s) listed in § 250.125, according to the instructions in § 250.126.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2010–0102]

RIN 1625–AA08

Special Local Regulation for Marine Events; Temporary Change of Dates for Recurring Marine Events in the Fifth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard proposes to temporarily change the enforcement period of special local regulations for recurring marine events in the Fifth Coast Guard District. These regulations apply to only two recurring marine events that conduct power boat races. Special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the Western Branch, Elizabeth River, VA, and North Atlantic Ocean, Ocean City, MD during each event.

DATES: *Effective Date:* This rule is effective in the CFR on April 19, 2010. This rule is effective with actual notice for purposes of enforcement from April 17, 2010 through May 31, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2010–0102 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0102 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call LT Tiffany Duffy, Project Manager, Sector Hampton Roads, Waterways Management Division, United States Coast Guard; telephone 757–668–5580, e-mail *Tiffany.A.Duffy@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because delaying the effective date would be contrary to the public interest since immediate action is needed to ensure the public's safety during the Virginia State Hydroplane Championships and the Geico Offshore Grand Prix.

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

Register. Delaying the effective date would be contrary to the public interest since immediate action is needed to ensure the public's safety during the Virginia State Hydroplane Championships and the Geico Offshore Grand Prix.

Basis and Purpose

Marine events are frequently held on the navigable waters within the boundary of the Fifth Coast Guard District. The on water activities that typically comprise marine events include sailing regattas, power boat races, swim races and holiday boat parades. For a description of the geographical area of each Coast Guard Sector—Captain of the Port Zone, *please see* 33 CFR 3.25.

This regulation temporarily changes the enforcement period of special local regulations for recurring marine events within the Fifth Coast Guard District. This regulation applies to two marine events in 33 CFR 100.501, Table to § 100.501.

On April 17 and 18, 2010, the Virginia Boat Racing Association will sponsor the "Virginia State Hydroplane Championship" hydroplane races on the waters of the Western Branch of the Elizabeth River near Portsmouth, Virginia. The regulation at 33 CFR 100.501 is effective annually for this river boat race marine event. The event will consist of approximately 60 hydroplane powerboats conducting high-speed competitive races on the Western Branch of the Elizabeth River in the vicinity of Portsmouth City Park, Portsmouth, Virginia. A fleet of spectator vessels is expected to gather near the event site to view the competition. To provide for the safety of participants, spectators, support and transiting vessels, the Coast Guard will temporarily restrict vessel traffic in the event area during the hydroplane races. The regulation at 33 CFR 100.501 would be enforced for the duration of the event. Under provisions of 33 CFR 100.501, from 9 a.m. to 5:30 p.m. on April 17 and 18, 2010, vessels may not enter the regulated area unless they receive permission from the Coast Guard Patrol Commander.

The Offshore Performance Association (OPA) Racing LLC annually sponsors the "Offshore Grand Prix", on the waters of the North Atlantic Ocean near Ocean City, MD. The regulation at 33 CFR 100.501 is effective annually for the Ocean City Offshore race marine event. The event is conducted on the waters of the North Atlantic Ocean along the shoreline near Ocean City, MD. The event consists of approximately 50 V-hull and twin-hull inboard hydroplanes racing in heats counter-clockwise around an oval race course. A fleet of spectator vessels is anticipated to gather nearby to view the competition. Therefore, to ensure the safety of participants, spectators and transiting vessels, 33 CFR 100.501 would be enforced for the duration of the event. Under provisions of 33 CFR 100.501, from 9:30 a.m. to 5 p.m. on May 30 and 31, 2010, vessels may not enter the regulated area unless they receive permission from the Coast Guard Patrol Commander. Due to the need for vessel control during the event, vessel traffic will be temporarily restricted to provide for the safety of participants, spectators and transiting vessels.

Discussion of Rule

The Coast Guard is establishing temporary special local regulations on specified waters of the Western Branch, Elizabeth River, near Portsmouth, Virginia; and North Atlantic Ocean near Ocean City, MD. The regulated areas will be established in the interest of public safety during the Virginia State Hydroplane Championships and the Geico Offshore Grand Prix, and will be enforced on April 17 until April 18, 2010, from 9 a.m. to 5:30 p.m. and on May 30 until May 31, 2010, from 9:30 a.m. to 5 p.m. Access to the safety zone will be restricted during the specified date and times or until the powerboat races are complete, whichever is sooner. Except for participants and vessels authorized by the Captain of the Port or his Representative, no person or vessel may enter or remain in the regulated area.

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.

Although this rule prevents traffic from transiting a portion of certain waterways during specified events, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via marine information broadcasts, local radio stations and area newspapers so mariners can adjust their plans accordingly. Additionally, this rulemaking does not change the permanent regulated areas that have been published in 33 CFR 100.501, Table to § 100.501. In some cases vessel traffic may be able to transit the regulated area when the Coast Guard Patrol Commander deems it is safe to do so.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in the areas where marine events are being held. This regulation will not have a significant impact on a substantial number of small entities because it will be enforced only during marine events that have been permitted by the Coast Guard Captain of the Port. The Captain of the Port will ensure that small entities are able to operate in the areas where events are occurring when it is safe to do so. This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) In some cases, vessels will be able to safely transit around the regulated area at various times; (ii) with the permission of the Patrol Commander, vessels may transit through the regulated area; and (iii) before the enforcement period, the Coast Guard will issue maritime advisories so mariners can adjust their plans accordingly.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can 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 (adjusted for inflation) 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 cause 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 Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, 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 this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction. This rule involves implementation of regulations within 33 CFR part 100 that apply to organized marine events on the navigable waters of the United States that may have potential for negative impact on the safety or other interest of waterway users and shore side activities in the event area. The category of water activities includes but is not limited to sail boat regattas, boat parades, power boat racing, swimming events, crew racing, and sail board racing.

Under figure 2–1, paragraph (34)(h), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 100

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

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

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

Authority: 33 U.S.C. 1233.

■ 2. In § 100.501, suspend line No. 31 and 38 in the Table to § 100.501.

■ 3. In § 100.501 on April 17 and 18, 2010, add line No. 58 in Table to § 100.501; on May 30 and 31, 2010, add line No. 59 in Table to § 100.501; to read as follows:

§ 100.501–T05–0102 Special Local Regulations; Marine Events in the Fifth Coast Guard District.

* * * * *

Table To § 100.501.—All coordinates listed in the Table to § 100.501 reference Datum NAD 1983.

COAST GUARD SECTOR HAMPTON ROADS—COTP ZONE

No.	Date	Event	Sponsor	Location
*	*	*	*	* * * *
58	April 17–April 18, 2010.	Virginia state hydroplane championships.	Virginia Boat Racing Association.	The waters of the Western Branch, Elizabeth River bounded by a line connecting the following points: latitude 36°50′06″ N, longitude 076°22′27″ W, thence to latitude 36°50′06″ N, longitude 076°21′57″ W, thence to latitude 36°50′15″ N, longitude 076°21′55.8″ W, thence to latitude 36°50′15″ N, longitude 076°22′27″ W, thence to point of origin.
59	May 30–May 31, 2010.	Ocean City Maryland Offshore Grand Prix.	Offshore Performance Association, OPA Racing, LLC.	The waters of the Atlantic Ocean commencing at a point on the shoreline at latitude 38°25′42″ N, longitude 075°03′06″ W; thence east southeast to latitude 38°25′30″ N, longitude 075°02′12″ W, thence south southwest parallel to the Ocean City shoreline to latitude 38°19′12″ N, longitude 075°03′48″ W; thence west northwest to the shoreline at latitude 38°19′30″ N, longitude 075°05′00″ W. The waters of the Atlantic Ocean bounded by a line drawn from a position along the shoreline near Ocean City, MD at latitude 38°22′25.2″ N, longitude 075°03′49.4″ W, thence easterly to latitude 38°22′00.4″ N, longitude 075°02′34.8″ W, thence southwesterly to latitude 38°19′35.9″ N, longitude 075°03′35.4″ W, thence westerly to a position near the shoreline at latitude 38°20′05″ N, longitude 075°04′48.4″ W, thence northerly along the shoreline to the point of origin.

* * * * *

Dated: April 7, 2010.

M.S. Ogle,

Captain, U.S. Coast Guard, Captain of the Port, Hampton Roads.

[FR Doc. 2010–8861 Filed 4–16–10; 8:45 am]

BILLING CODE 9110–04–P

Proposed Rules

Federal Register
Vol. 75, No. 74
Monday, April 19, 2010

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.

RECOVERY ACCOUNTABILITY AND TRANSPARENCY BOARD

4 CFR Part 200

RIN 0430–AA03

Privacy Act Regulations

AGENCY: Recovery Accountability and Transparency Board.

ACTION: Proposed rule.

SUMMARY: The Recovery Accountability and Transparency Board (Board) proposes to amend the Board's regulations implementing the Privacy Act of 1974 (Privacy Act), as amended. This proposed rule would exempt certain systems of records from certain sections of the Privacy Act. These exemptions will help ensure that the Board may efficiently and effectively compile investigatory material to prevent and detect fraud, waste, and abuse and perform its other authorized duties and activities relating to oversight of funds awarded pursuant to the American Recovery and Reinvestment Act of 2009 (Recovery Act).

DATES: Comments on the proposed rule should be submitted no later than June 18, 2010.

ADDRESSES: Comments on this proposed rule may be submitted:

- *By Mail or Hand Delivery:* Office of General Counsel, Recovery Accountability and Transparency Board, 1717 Pennsylvania Avenue, NW., Suite 700, Washington, DC, 20006;
- *By Fax:* (202) 254–7970; or
- *By E-mail to the Board: comments@ratb.gov.*

All comments on this proposed Privacy Act rule should be clearly identified as such.

FOR FURTHER INFORMATION CONTACT: Jennifer Dure, General Counsel, (703) 487–5439.

SUPPLEMENTARY INFORMATION: On November 20, 2009, the Board published in the **Federal Register** proposed system notices to establish new systems of records, "RATB—11—RATB Investigative Files" and "RATB—12—RATB Fraud Hotline Program Files," pursuant to the Privacy Act, as amended (74 FR 60302, Nov. 20, 2009). The Board received no comments on these proposed systems of records. The following proposed amendments of the Board's Privacy Act regulations, 4 CFR part 200, exempt these systems of records from certain provisions of the Privacy Act which require, among other things, that the Board provide notice when collecting information, account for certain disclosures, permit individuals access to their records, and allow them to request that the records be amended. These provisions would interfere with the Board's oversight functions if applied to the Board's maintenance of these systems of records.

Accordingly, it is proposed to exempt these systems of records from specified provisions of the Privacy Act, pursuant to sections 552a(j)(2), (k)(2) and (k)(5).

List of Subjects in 4 CFR Part 200

Privacy Act of 1974.

For the reasons set forth in the preamble, the Board proposes to amend Chapter II of Title 4, Code of Federal Regulations, as follows:

CHAPTER II—RECOVERY ACCOUNTABILITY AND TRANSPARENCY BOARD

PART 200—PRIVACY ACT OF 1974

1. The authority for Part 200 continues to read as follows:

Authority: 5 U.S.C. 552a(f).

2. Add § 200.17 to read as follows:

§ 200.17 Exemptions.

(a) *General policy.* The Privacy Act permits an agency to exempt certain types of systems of records from some of the Privacy Act's requirements. It is the policy of the Board to exercise authority to exempt systems of records only in compelling cases.

(b) *Specific systems of records exempted under (j)(2) and (k)(2).* The Board exempts the RATB Investigative Files (RATB—11) system of records from the following provisions of 5 U.S.C. 552a:

(1) From subsection (c)(3) because the release of accounting of disclosure would inform a subject that he or she is under investigation. This information would provide considerable advantage to the subject in providing him or her with knowledge concerning the nature of the investigation and the coordinated investigative efforts and techniques employed by the cooperating agencies. This would greatly impede the Board's criminal law enforcement duties.

(2) From subsection (c)(4) and (d) because notification would alert a subject to the fact that an open investigation on that individual is taking place, and might weaken the ongoing investigation, reveal investigatory techniques, and place confidential informants in jeopardy.

(3) From subsection (e)(1) because the nature of the criminal and/or civil investigative function creates unique problems in prescribing a specific parameter in a particular case with respect to what information is relevant or necessary. Also, due to the Board's close working relationship with other Federal, State and local law enforcement agencies, information may be received which may relate to a case under the investigative jurisdiction of another agency. The maintenance of this information may be necessary to provide leads for appropriate law enforcement purposes and to establish patterns of activity which may relate to the jurisdiction of other cooperating agencies.

(4) From subsection (e)(2) because collecting information to the fullest extent possible directly from the subject individual may or may not be practical in a criminal and/or civil investigation.

(5) From subsection (e)(3) because supplying an individual with a form containing a Privacy Act Statement would tend to inhibit cooperation by many individuals involved in a criminal and/or civil investigation. The effect would be somewhat adverse to established investigative methods and techniques.

(6) From subsection (e)(4)(G)–(I) because this system of records is exempt from the access provisions of subsection (d).

(7) From subsection (e)(5) because the requirement that records be maintained with attention to accuracy, relevance, timeliness, and completeness would unfairly hamper the investigative process. It is the nature of law enforcement for investigations to uncover the commission of illegal acts at diverse stages. It is frequently impossible to determine initially what

information is accurate, relevant, timely, and least of all complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light.

(8) From subsection (e)(8) because the notice requirements of this provision could present a serious impediment to law enforcement by revealing investigative techniques, procedures, and existence of confidential investigations.

(9) From subsection (f) because the agency's rules are inapplicable to those portions of the system that are exempt and would place the burden on the agency of either confirming or denying the existence of a record pertaining to a requesting individual, which might in itself provide an answer to that individual relating to an ongoing investigation. The conduct of a successful investigation leading to the indictment of a criminal offender precludes the applicability of established agency rules relating to verification of record, disclosure of the record to that individual, and record amendment procedures for this record system.

(10) For comparability with the exemption claimed from subsection (f), the civil remedies provisions of subsection (g) must be suspended for this record system. Because of the nature of criminal investigations, standards of accuracy, relevance, timeliness, and completeness cannot apply to this record system. Information gathered in an investigation is often fragmentary, and leads relating to an individual in the context of one investigation may instead pertain to a second investigation.

(c) *Specific systems of records exempted under (k)(2) and (k)(5).* The Board exempts the RATB Fraud Hotline Program Files (RATB—12) system of records from the following provisions of 5 U.S.C. 552a:

(1) From subsection (c)(3) because disclosures from this system could interfere with the just, thorough and timely resolution of the complaint or inquiry, and possibly enable individuals to conceal their wrongdoing or mislead the course of the investigation by concealing, destroying or fabricating evidence or documents.

(2) From subsection (d) because disclosures from this system could interfere with the just, thorough and timely resolution of the complaint or inquiry, and possibly enable individuals to conceal their wrongdoing or mislead the course of the investigation by concealing, destroying or fabricating evidence or documents. Disclosures could also subject sources and witnesses to harassment or intimidation which jeopardize the safety and well-being of themselves and their families.

(3) From subsection (e)(1) because the nature of the investigatory function creates unique problems in prescribing specific parameters in a particular case as to what information is relevant or necessary. Due to close working relationships with other Federal, state and local law enforcement agencies, information may be received which may relate to a case under the investigative jurisdiction of another government agency. It is necessary to maintain this information in order to provide leads for appropriate law enforcement purposes and to establish patterns of activity which may relate to the jurisdiction of other cooperating agencies.

(4) From subsection (e)(4)(G)–(H) because this system of records is exempt from the access provisions of subsection (d).

(5) From subsection (f) because the agency's rules are inapplicable to those portions of the system that are exempt and would place the burden on the agency of either confirming or denying the existence of a record pertaining to a requesting individual might in itself provide an answer to that individual relating to an on-going investigation. The conduct of a successful investigation leading to the indictment of a criminal offender precludes the applicability of established agency rules relating to verification of record, disclosure of the record to that individual, and record amendment procedures for this record system.

Ivan J. Flores,

Paralegal Specialist, Recovery Accountability and Transparency Board.

[FR Doc. 2010–8912 Filed 4–16–10; 8:45 am]

BILLING CODE 6820–GA–P

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 831, 841

RIN 3206–AM17

RAILROAD RETIREMENT BOARD

20 CFR Part 350

RIN 3220–AB63

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404, 416

RIN 0960–AH18

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 212

RIN 1505–AC20

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AN67

Garnishment of Accounts Containing Federal Benefit Payments

AGENCY: Department of the Treasury, Fiscal Service (Treasury); Social Security Administration (SSA); Department of Veterans Affairs (VA); Railroad Retirement Board (RRB); Office of Personnel Management (OPM).

ACTION: Joint notice of proposed rulemaking.

SUMMARY: Treasury, SSA, VA, RRB and OPM (Agencies) are publishing for comment a proposed rule to implement statutory restrictions on the garnishment of Federal benefit payments. The Agencies are taking this action in response to recent developments in technology and debt collection practices that have led to an increase in the freezing of accounts containing Federal benefit payments. The proposed rule would establish procedures that financial institutions must follow when a garnishment order is received for an account into which Federal benefit payments have been directly deposited. The proposed rule would require financial institutions that receive a garnishment order for an account to determine whether any Federal benefit payments were deposited to the account within 60 calendar days prior to receipt of the order and, if so, would require the financial institution to ensure that the account holder has access to an amount equal to the sum of such payments in

the account or to the current balance of the account, whichever is lower.

DATES: Comments must be received on or before June 18, 2010.

ADDRESSES: The Agencies invite comments on all aspects of this proposed rule. In accordance with the U.S. government's eRulemaking Initiative, the Agencies publish rulemaking information on *http://www.regulations.gov.* Regulations.gov offers the public the ability to comment on, search, and view publicly available rulemaking materials, including comments received on rules.

The Agencies will jointly review all of the comments submitted. Comments on this rule must only be submitted using the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions on the Web site for submitting comments.
- *Mail:* Gary Grippo, Deputy Assistant Secretary, Fiscal Operations and Policy, U.S. Department of the Treasury, 1500 Pennsylvania Avenue, NW., Room 2112, Washington, DC 20220.

Instructions: All submissions received must include the Agencies' names and RIN numbers 3206–AM17, 3220–AB63, 0960–AH18, 1505–AC20, and 2900–AN67 for this rulemaking. In general, comments received will be published on Regulations.gov without change, including any business or personal information provided. Treasury will also make such comments available for public inspection and copying in Treasury's Library, Room 1428, Department of the Treasury, 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 comments by telephoning (202) 622–0990. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Gary Grippo, Deputy Assistant Secretary, Fiscal Operations and Policy, U.S. Department of the Treasury, at (202) 622–6222, or e-mail questions to *garnishment@do.treas.gov.*

SUPPLEMENTARY INFORMATION: The Agencies are proposing to adopt a rule to address concerns associated with the garnishment of exempt Federal benefit payments, including Social Security benefits, Supplemental Security Income (SSI) benefits, VA benefits, Federal Railroad retirement benefits, Federal Railroad unemployment and sickness benefits, Civil Service Retirement System benefits and Federal Employees Retirement System benefits. These benefits, which are generally exempt under Federal law from garnishment orders and the claims of judgment creditors, often constitute a major portion, and sometimes all, of an individual's income. As a result, when financial institutions receive garnishment orders and place freezes on accounts containing exempt Federal benefit payments, the recipients of these funds can face significant hardship. At the same time, financial institutions are required by law to comply with garnishment orders, which may necessitate placing a freeze on an account that contains Federal benefit payments. The Agencies are proposing to adopt a rule that would set forth straightforward, uniform procedures for financial institutions to follow in order to minimize the hardships encountered by Federal benefit payment recipients whose accounts are frozen pursuant to a garnishment order.

I. Background

Social Security benefits, SSI benefits, VA benefits, Federal Railroad Retirement benefits, Federal Railroad unemployment and sickness benefits, Civil Service Retirement System benefits and Federal Employees Retirement System benefits are protected under Federal law from garnishment and the claims of judgment creditors.[1] For example, Section 207 of the Social Security Act provides that moneys paid or payable as Old-Age, Survivors, and Disability Insurance (OASDI) benefits are not "subject to execution, levy, attachment, garnishment, or other legal process."[2] Similarly, VA benefits are exempt, in most cases, from "attachment, levy, or seizure by or under any legal or equitable process whatever, either before or after receipt by the beneficiary" under a separate section of the United States Code.[3] Federal Railroad Retirement benefits, Federal Railroad unemployment and sickness benefits, Civil Service Retirement System benefits and Federal Employees Retirement System benefits are similarly protected under Federal law.[4]

Creditors and debt collectors are often able to obtain court orders garnishing funds in an individual's account at a financial institution. Neither the creditor nor the court issuing the order may know whether an account contains Federal benefit payments. To comply with court garnishment orders and preserve funds subject to the orders, financial institutions often place a temporary freeze on an account upon receipt of a garnishment order. Although state laws provide account owners with an opportunity to assert any rights, exemptions, and challenges to the garnishment order, including the exemptions under applicable Federal benefits laws, the freezing of funds during the time it takes to file and adjudicate such a claim can cause significant hardship for account owners. This is especially true when, as is often the case, the recipient of Federal benefits depends on these funds as his or her primary or sole source of income. Recent statistics show that 32 percent of Social Security beneficiary married couples or nonmarried persons age 65 or older reported receiving 90 percent or more of their income from Social Security. In addition, Social Security benefits are the primary source of income (representing 50 percent or more of total income) for 64 percent of beneficiary married couples or nonmarried persons age 65 or older.[5] If their accounts are frozen, these individuals may find themselves without access to the funds in their account unless and until they contest the garnishment order in court, a process that can be confusing, protracted and expensive.

At the same time, financial institutions are required by law to comply with garnishment orders. A financial institution that fails to preserve and remit funds may be at risk of being held in contempt of court. In many cases, a financial institution would be liable for any funds that are withdrawn by an account holder after the financial institution has received a garnishment order for the account.

It can be difficult for a financial institution to determine whether an account contains Federal benefit payments that are exempt from garnishment ("exempt funds" or "exempt payments"). A financial institution may not understand the

[1] *See* 42 U.S.C. 407(a); 42 U.S.C. 1383(d)(1); 38 U.S.C. 5301(a); 45 U.S.C. 231m(a); 45 U.S.C. 352(e); 5 U.S.C. 8346(a) and 5 U.S.C. 8470.

[2] 42 U.S.C. 407.

[3] 38 U.S.C. 5301(a)(1).

[4] 45 U.S.C. 231m(a); 45 U.S.C. 352(e); 5 U.S.C. 8346; 5 U.S.C. 8470.

[5] Annual Statistical Supplement to the Social Security Bulletin, 2008 Social Security Administration Office of Retirement and Disability Policy Office of Research, Evaluation, and Statistics SSA Publication No. 13–11700. Released: March 2009.

Automated Clearing House[6] (ACH) batch header fields that accompany direct deposit payments and identify different Federal benefit programs, and thus the institution will not necessarily conclude from the information available to it that a direct deposit payment is an exempt payment. Identifying exempt payments can be even more challenging when an account holder deposits checks representing benefit payments to an account. To determine whether a check representing exempt funds was deposited to an account, a financial institution would have to review images of the deposit tickets and the checks deposited to the account—a manual, time-consuming, and costly process.

One of the biggest obstacles to determining whether an account contains exempt funds arises when both exempt funds and non-exempt funds have been deposited to an account. In such cases, there is no single, consistently applied accounting standard to determine the proportion of the commingled funds that should be protected from garnishment. For example, if a $1000 exempt payment is deposited to John Doe's account on May 1, followed by a $300 withdrawal on May 2, a $200 deposit of non-exempt funds on May 3, and a $400 withdrawal on May 4, it is not clear what amount of money is exempt from a garnishment order received on May 5. If a first-in, first-out method of identifying funds is used, $300 would be exempt.[7] An alternative approach would result in the determination that $500 would be exempt.[8] Yet a third approach would result in a determination that $389 would be exempt.[9]

In addition, garnishment orders may not provide sufficient information to allow financial institutions to know if an order is subject to one of the exceptions allowing garnishment of Federal benefit payments.

As a result of these complexities, many financial institutions have concluded that they are not in a position to evaluate the extent to which funds in an account are protected from garnishment, and that attempting to do so may expose them to liability. The account holder is thus left to assert in court any Federal law protections that may be available to exempt funds in an account, resulting in the hardships discussed above.

II. Overview of Proposed Rule

To address the foregoing problems, the Agencies are proposing to adopt a new rule. The primary goals of the proposed rule are (1) to ensure that benefit recipients have access to exempt funds while garnishment orders are complied with, adjudicated, or otherwise resolved; (2) to protect financial institutions from liability when, having received a garnishment order for an account receiving Federal benefit payments, they allow the account holder access to exempt funds in the account; and (3) to establish straightforward, uniform, cost effective procedures addressing the extent to which financial institutions may, pursuant to garnishment orders, freeze or seize funds in accounts that contain Federal benefits. The rule would protect financial institutions that follow specified procedures from the risk of liability, contempt of court, or civil penalties when they permit account holders to access funds in the account in accordance with the requisite procedures. The rule would not limit an account holder's right to assert any additional protections against garnishment that might be available under Federal or state law. The Agencies seek comment on all aspects of the proposed rule.

Procedural Instructions for Financial Institutions

The proposed rule is largely structured as a series of straightforward actions that a financial institution must carry out upon receipt of a garnishment order. The first step in the sequence is to determine if the United States is the plaintiff that obtained the order against an account holder. For the reasons discussed in more detail below, the proposed rule has an exclusion for those cases where a Federal entity is the creditor.

Account Review and Lookback Period

The second step for a financial institution that receives a garnishment order for an account would be to review the account history during the 60-day period that precedes the receipt of the garnishment order. If, during this "lookback period," one or more exempt payments were directly deposited to the account, the financial institution must allow the account holder to have access to an amount equal to the lesser of the sum of such exempt payments or the balance of the account on the date of the account review (the "protected amount"). The financial institution must notify the account holder of the protections from garnishment that apply to exempt funds. The Agencies are proposing that the lookback period be 60 calendar days to provide financial institutions with a reasonable and easily applied boundary for the account review, and so that the last two cycles of benefit payments under any of the Agencies' programs are generally covered. The Agencies welcome comment on the definition and effects of the proposed lookback period.

The Agencies considered using a uniform, flat amount in the definition of the protected amount that would apply in all cases where a benefit payment was deposited to an account during the lookback period. For example, the Agencies considered a policy that the protected amount would mean the lesser of (i) $2,200 or (ii) the balance in the account on the date of account review. This approach of establishing a standard protected amount of $2,200 would provide certainty, clarity, and administrative simplicity for all parties. However, the Agencies are concerned that such a definition may go beyond the underlying statutory authorities to protect "moneys paid" and would result in the unauthorized over-protection of funds when benefit payments were less than the flat amount, or when the funds in the account could not be reasonably traced back to earlier benefit payments. The Agencies welcome comment on the underlying statutory authority and the definition of the protected amount.

If an individual has multiple accounts at a financial institution, the proposed rule would require a separate account review, and the establishment of a separate protected amount, for each account. Further, in some cases an individual with multiple accounts may make one-time or recurring transfers between accounts. If an exempt payment is directly deposited into one

[6] The Automated Clearing House is the nationwide electronic fund transfer system that provides for the inter-bank clearing of direct deposit transactions and for the exchange of payment-related information among participating financial institutions.

[7] There are $1000 in exempt funds at end of May 1; $700 in exempt funds at end of May 2; and $700 in exempt funds and $200 in non-exempt funds at end of May 3. On May 4, the $400 withdrawal is applied against the first funds that were deposited to the account, *i.e.,* the remaining $700 exempt amount. Under this approach, there would be an exempt amount of $300 on May 5.

[8] There are $1000 in exempt funds at end of May 1; $700 in exempt funds at end of May 2; and $700 in exempt funds and $200 in non-exempt funds at end of May 3. The May 4 $400 withdrawal is allocated equally to the exempt and non-exempt funds, *i.e.,* $200 is treated as being withdrawn from the exempt funds and $200 is treated as being withdrawn from the non-exempt funds, for an exempt amount of $500 on May 5.

[9] There are $1000 in exempt funds at end of May 1; $700 in exempt funds at end of May 2; $700 in exempt funds and $200 in non-exempt funds at end of May 3. On May 4, the $400 withdrawal is treated as occurring in proportion to the nature of the funds in the account, i.e., 7/9 of the withdrawal, or $311, is treated as withdrawn from the exempt funds and 2/9 of the withdrawal, or $89, is treated as withdrawn from the non-exempt funds. Under this approach, $389 would be exempt on May 5.

account and funds from that account are subsequently transferred to a second account, the financial institution would have no requirement to trace funds into the second account or to establish a protected amount in the second account as a result of the transfer. The account review on the second account would be performed independent of the first account based on an examination for directly deposited Federal benefit payments, not account transfers. The Agencies request comment on this aspect of the proposed rule.

Process for Identifying Exempt Funds

The Agencies will do two things to assist financial institutions to determine whether exempt funds were directly deposited during the lookback period. First, Treasury will encode an "X" in position 20 of the "Company Name" Field of the Batch Header Record for each Agency exempt benefit Automated Clearing House (ACH) payment. For example, a typical Social Security benefit payment would have a company name of "US TREASURY 303X." This encoding, along with the current practice of encoding a "2" in the "Originator Status Code" Field in the Batch Header Record to designate payments originated from the Federal government, will allow financial institutions to identify Federal exempt payments through either manual or systems inspection.

Second, the Agencies will publish a list of the unique "Entry Detail Description" Fields in the Batch Header Record for all of their exempt benefit payments. For example, the "SUPP SEC" entry denotes an exempt Supplemental Security Income benefit payment, and "VA CH31" denotes an exempt VA Vocational Rehabilitation & Education benefit payment.

Because information in the "Company Name" and the "Entry Detail Description" Fields is typically included on the account holder's bank statement, financial institutions should also be able to visually identify an exempt payment using a standard customer service or account maintenance screen.

Treasury will update the Green Book, *A Guide to Federal Government ACH Payments and Collections,* to reflect these mechanisms for identifying exempt Federal payments, and financial institutions will be able to rely on this combination of identifiers to determine whether exempt payments were deposited to an account during the lookback period.

Financial institutions would not be required to research checks to determine whether a Treasury check representing an exempt payment was deposited to an account. The Agencies are not proposing to address checks within the rule for two reasons. First, checks do not appear to raise the same concerns raised by the direct deposit of exempt funds. A benefit recipient who receives a Treasury check representing exempt funds can choose to cash the check rather than to deposit the check and take on the risk that the funds will be garnished. In contrast, direct deposit by its very definition involves the depositing of the payment to an account without the intermediate step in which the payment beneficiary receives the payment instrument and has physical control of its disposition through endorsement and negotiation. Second, there is no way currently for financial institutions to readily identify whether a Treasury check that was deposited to an account represents exempt funds. Whereas the Agencies are proposing the inclusion of identifiers for directly deposited payments, there is no equivalent approach that would make it possible for financial institutions to determine whether a Treasury check represents an exempt payment. Even if the Agencies could develop a way for an identifier to be included on a Treasury check, a financial institution would need to manually pull up images or copies of recent items to find Treasury checks and visually inspect them.

The fact that the rule would not address Treasury checks in no way affects an individual's right to assert or receive an exemption from garnishment by following the procedures specified under the applicable law. Indeed, nothing in the proposed rule in any way limits or restricts an account holder's right to assert a claim that any or all funds in an account are protected from garnishment under Federal or state law, including funds deposited by check or a balance in the account in excess of the protected amount.

Discretionary Account Freezes

The Agencies are aware that a minority of jurisdictions may permit, but not require, financial institutions to respond to a garnishment order by placing a freeze on the judgment debtor's entire account or on an amount of account funds greater than that which the financial institution is directed to sequester by court order. The proposed rule would preclude financial institutions from placing freezes on protected funds in all circumstances, even when the freeze is discretionary in the sense of not being compelled by court order or state statute or regulation. Financial institutions may undertake such "discretionary" freezes covering amounts in excess of the judgment debt as a protective measure to limit the financial institution's liability for releasing other funds to the account holder, or because the financial institution is unaware of which funds in the account are exempt from garnishment.

As already discussed, Federal law protects Federal benefits payments from garnishment, seizure, or other legal process.[10] Some federal and state courts have found that in certain circumstances a temporary freeze on an account containing exempt funds may violate Federal anti-garnishment statutes. *See, e.g., Finberg* v. *Sullivan,* 634 F.2d 50 (3d Cir. 1980); *Mayers* v. *N.Y. Cmty. Bancorp, Inc.,* No. CV–03–5837, 2005 U.S. Dist. LEXIS 20279 (E.D.N.Y. Aug. 13, 2005); *Brosamer* v. *Mark,* 540 N.E.2d 652 (Ind. Ct. App. 1989). Although the Agencies considered limiting the rule to only those freezes mandated by court order or state statute or regulation, there is concern that in light of the legal uncertainty such a limited rule could not be fashioned in a manner that would protect exempt funds from being frozen. The Agencies have therefore determined that the only way to protect exempt funds from being subjected to garnishment, seizure, or other legal process is to preclude financial institutions from placing freezes on protected funds in all circumstances.

Direct Service on Agencies for Alimony and Child Support Obligations

Under the proposed rule, financial institutions would not be responsible for determining the purpose of a garnishment order, including whether the order seeks to collect child support or alimony obligations. Financial institutions would calculate the protected amount and ensure that the protected amount is not frozen, and would be protected from any liability for taking this action.

Parties seeking to garnish Federal benefit payments for alimony or child support obligations would not be foreclosed from recovering these amounts, however, as they can pursue these benefits directly by garnishing benefit payments before they are made by the Agency issuing the payment. *See* 42 U.S.C. 659. SSA, VA, RRB and OPM each accept service of process of garnishment orders for child support and alimony, and will give effect to such orders if the payments that are the

[10] *See* 42 U.S.C. 407(a); 42 U.S.C. 1383(d)(1); 38 U.S.C. 5301(a); 45 U.S.C. 231m(a); 45 U.S.C. 352(e); 5 U.S.C. 8346(a) and 5 U.S.C. 8470.

subject of the order can legally be garnished for these purposes.[11]

Protected Amount

The Agencies are proposing that the protected amount be the lesser of (1) the sum of all benefit payments directly deposited to the account during the lookback period, or (2) the balance in the account on the day when the financial institution reviews the account history.[12] As described above, the intent of the 60-day lookback period is to ensure that two benefit payment cycles are generally captured and thus produce in most cases a protected amount equal to twice the monthly benefit amounts. The Agencies welcome comment on this definition of the protected amount.

It is important to note that the protected amount is not the same as the amount of funds that may ultimately be exempt from garnishment. The proposed rule would not prevent or limit a benefit recipient from challenging a garnishment order; it would simply prevent the freezing of a lifeline amount of exempt funds. Thus, if a benefit recipient believed that an account contained exempt funds in excess of the protected amount, the recipient could follow the procedures established under the applicable law to contest the garnishment.

Continuing Garnishments

A small number of states authorize the issuance of a "continuing" garnishment order, *i.e.,* an order requiring the garnishee to monitor, preserve and remit funds coming into the garnishee's custody on an ongoing basis.[13] Under the proposed rule, a financial institution that receives a garnishment order for an account containing a protected amount would have no continuing obligation to garnish amounts deposited or credited to the account following the date of account review, and would not be permitted to take any action to freeze any amounts subsequently deposited or credited unless served a new or different garnishment order. In effect, the proposed rule would partially preempt state law by converting an ongoing garnishment order into a one-time garnishment order and prohibiting the financial institution from complying with the order's ongoing requirements.

This partial preemption is necessary to give effect to the protections in the anti-garnishment statutes, since it is not feasible to implement both a protected amount and to permit continuing garnishment. Unlike one-time garnishment orders, with respect to which a financial institution may comply by reviewing prior deposits in an accounting system during a defined lookback period, continuing garnishment orders would require financial institutions to take action on each future deposit. That is, a benefit payment could be protected only if financial institutions monitored new deposits in real time, or at least daily, to assess which are exempt and which are not exempt from garnishment, to be sure that exempt funds are never frozen. The Agencies believe that a policy of requiring financial institutions to monitor deposits daily would be neither operationally nor economically feasible, and would put financial institutions in the untenable position of having to choose between noncompliance with the rule, by freezing accounts, or noncompliance with the continuing garnishment order, by allowing the account holder access to all funds. Even if it were possible to implement such a policy in a manner consistent with the anti-garnishment statutes, its costs and burdens could result in benefit recipients finding it difficult to obtain banking services. Accordingly, the proposed rule necessarily preempts the requirements of continuing garnishment in cases where a benefit payment was deposited into an account during the lookback period. The Agencies note, however, that while the proposed rule preempts the continuing garnishment of an account pursuant to one court order, creditors are not restricted from obtaining, and courts are not prohibited from issuing, discrete new garnishment orders against the same account over time.

Garnishment Fees

The proposed rule would prohibit financial institutions from charging garnishment fees against protected amounts. For an account that contains a protected amount, the financial institution would be permitted to collect a garnishment fee only against funds in the account in excess of the protected amount on the date of the account review, and only if the financial institution customarily charges its other account holders a garnishment fee of the same nature and in the same amount. Financial institutions would not be permitted to charge garnishment fees that are specific to accounts to which exempt payments are deposited. In addition, for accounts containing a protected amount, a financial institution would not be permitted to charge or collect a garnishment fee after the date of account review. Thus, a financial institution could not defer a garnishment fee until future deposits are received in the account.

Notice to Account Owner

To ensure that recipients are aware of their rights to challenge a garnishment order, financial institutions would be required to deliver a notice explaining these rights to the owner of any account for which the financial institution conducted an account review and to which an exempt payment was directly deposited during the lookback period. The notice, which would have to include certain information set forth in the proposed rule, would be required to be sent within two business days of the completion of the account review. The proposed rule contains a model notice. Financial institutions would not be required to use the model notice, but those that choose to do so would be deemed to be in compliance with the notice content requirements set forth in the rule.

Safe Harbor for Financial Institutions

The proposed rule would provide a safe harbor for financial institutions that comply with the required procedures. A financial institution that makes available the protected amount to an account holder in accordance with the rule's requirements would not be at risk of contempt of court or liability to a judgment creditor. The proposed rule would preempt any state or local government law or regulation that is inconsistent with the proposed rule, but only to the extent that an inconsistency would prevent a financial institution from complying with the requirements of the proposed rule. Some state laws, for example, may protect from garnishment funds in a bank account in an amount that exceeds the protected amount. The proposed rule does not displace or supersede such a state law requirement.

Treatment of Garnishment Orders Obtained by the United States

As described above, in cases where the United States is the plaintiff that has obtained a garnishment order against an account holder, the proposed rule would not require the financial institution to perform an account review or establish a protected amount. The Agencies are adopting this categorical exclusion of garnishment orders

[11] *See* 5 CFR part 581; *see also,* 20 CFR 404.1820; SSA Program Operations Manual System GN 02410.200–.210; 20 CFR part 350; and VA Veterans Benefits Administration Manual Rewrite M21–1MR, part III, subpart v, chapter 3, section C.13.

[12] If the balance in the account is zero or if the account balance is negative, there would be no protected amount.

[13] *See, e.g.,* NY Civil Prac L & R 5222(b); Pa. R. Civil P. 3111(c).

obtained by the United States for two reasons.

First, while the statutes that prohibit the garnishment of Federal benefit payments apply in some instances when the United States is a creditor, there are several Federal statutes that expressly permit the United States to garnish such payments in other instances. These statutes permitting the United States to garnish Federal benefits payments include 18 U.S.C. 3613(a), 26 U.S.C. 6334(c), 31 U.S.C. 3716(c)(3)(A)(i), and 42 U.S.C. 1320a–8(e)(1)(C). Absent a carve-out for all garnishment orders obtained by the United States, financial institutions would face uncertainty and the burden of determining which authority applied in a given instance.

Second, garnishments obtained by the United States are already governed by a comprehensive Federal statute that would overlap with certain provisions in the proposed rule and conflict with others. The Federal Debt Collection Procedures Act (FDCPA), 28 U.S.C. 3001 *et seq.,* establishes a uniform framework with exclusive civil procedures for the collection of all judgments due the United States, including cases where the United States is prohibited from garnishing Federal benefit payments as well as cases where it is expressly allowed to garnish such payments. *See* H.R. Rep. No. 101–736, at 32 (1990) ("the purpose of [the FDCPA] is to create a comprehensive statutory framework for the collection of debts owed to the United States government. Creation of a uniform Federal framework for the collection of Federal debts in the Federal Courts will improve the efficiency and speed in collection of those debts* * *").

While the proposed rule is needed to address the problems of garnishing exempt funds, it would both overlap and conflict with the framework of the FDCPA unless garnishment orders obtained by the United States are excluded. For example, the FDCPA includes numerous procedural protections for debtors who owe money to the United States that are intended to achieve similar goals as the proposed rule. It allows a debtor to exempt certain property from a money judgment based on either bankruptcy law or other non-bankruptcy Federal, State and local law, including the debtor's right to receive various benefits, maintenance payments, and pensions and annuities. *See* 28 U.S.C. 3014 and 11 U.S.C. 552(d). In addition, section 212.6(f) of the proposed rule would conflict with the FDCPA by providing that financial institutions shall have no continuing or periodic garnishment responsibilities. The FDCPA requires garnishment orders to be continuing. *See* 28 U.S.C. 3104(a), 3205(a). If both the FDCPA and the proposed rule applied to the same garnishment orders, confusion would likely arise from the overlapping and conflicting provisions. Additional procedural steps are needed to harmonize the two authorities.

Therefore, in light of the express authority of the United States to garnish Federal benefit payments in certain instances, the protections already guaranteed debtors under the FDCPA in all instances, and the confusion that would arise from having a rule with exceptions to comply with conflicting Federal statutes, the Agencies have chosen to establish a bright-line, procedural exclusion for garnishment orders obtained by the United States.

With such orders, financial institutions would not be required to perform an account review or take actions otherwise required by the proposed rule. Rather, the proposed rule would direct financial institutions to follow their customary procedures for garnishment orders and treat the relevant account(s) as if no Federal benefit payment were present. Financial institutions could rely on the naming of the "United States of America," "United States," or "U.S." as the plaintiff in the caption of the order, or on a standard certification that a Federal entity attaches to the order, to easily determine if the garnishment order was obtained by the United States. The proposed rule would provide a safe harbor for financial institutions that comply with the procedures required by the proposed rule.

Finally, the Agencies note that the United States obtains all garnishment orders in Federal court. Thus, although the proposed rule establishes an exclusion for garnishment orders obtained by the United States, it still fulfills the goal of providing financial institutions with a uniform national policy for handling garnishment orders issued by all state courts. The Agencies invite comments on all aspects of this policy on garnishment orders obtained by the United States.

Notwithstanding the need for this exclusion, to the extent that a Federal benefit payment is exempt from a garnishment order obtained by the United States, this exclusion does not alter such exempt status, or an individual's right to assert an exemption, that may exist under Federal law.

Enforcement

The Federal banking agencies (the Comptroller of the Currency, Federal Deposit Insurance Corporation, Federal Reserve Board, and Office of Thrift Supervision) and the National Credit Union Administration have authority under the Federal Deposit Insurance Act (12 U.S.C. 1818) and the Federal Credit Union Act (12 U.S.C. 1786), respectively, to pursue enforcement actions against insured depository institutions and insured credit unions for violations of law, rule or regulation. The provisions of the rule that would be applicable to insured depository institutions and insured credit unions would be subject to such enforcement authority.

III. Section-by-Section Analysis for 31 CFR Part 212

The provisions of the proposed rule would be set forth in a new part 212 to 31 CFR. SSA, VA, RRB and OPM are each proposing to amend their existing regulations to include a cross-reference to 31 CFR Part 212.

Section 212.1

Section 212.1 sets forth the purposes of the proposed rule.

Section 212.2

The proposed rule would apply to every entity defined as a financial institution, if the financial institution holds accounts to which benefit payments are directly deposited by one or more of the Agencies.

Section 212.3

Various terms used in the proposed regulation are defined in section 212.3. "Account" is defined to mean any account held by a financial institution to which benefit payments can be delivered by direct deposit. If a financial institution holds an account that does not have the capability to receive direct deposit payments, then that account would not fall within the definition, and the proposed rule would not apply to the financial institution's handling of the order.

For the reasons discussed above, "benefit payment" is defined as a direct deposit payment, and not a check payment. Accordingly, financial institutions would not need to identify benefit checks deposited to an account, and any such deposits would not be considered in determining whether there is a protected amount.

"Financial institution" is defined as a bank, savings association, credit union or other entity chartered under Federal or state law to engage in the business of banking. The definition is intended to be very broad, in order to capture any financial institution that might hold an account to which Federal benefits may be directly deposited. The Agencies

request comment on whether the proposed definition is appropriate.

The definition of "garnish" and "garnishment" are based on the wording of Agency statutes establishing the exemption of certain Federal benefit payments from garnishment. "Garnishment fee" is broadly defined to mean any kind of a fee that a financial institution charges to an account holder related to the receipt or processing of a garnishment order. "Garnishment order" and "order" are defined to mean a writ, order notice, summons, or similar written instruction issued by a court to effect a garnishment.

"Lookback period" is defined to mean the 60 calendar-day period preceding the date on which a financial institution is served a garnishment order. The Agencies are proposing that the lookback period be 60 calendar days long in order to generally cover the last two cycles of benefits paid under any of the Agencies' programs.

"Protected amount" is defined as the lesser of (i) the sum of all benefit payments deposited to the account during the lookback period or (ii) the balance in an account on the date of account review. Under this definition, there would not be a protected amount if the account balance is zero or the account is overdrawn.

"State" is defined to mean a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, or the United States Virgin Islands.

Section 212.4

Section 212.4 of the proposed rule sets forth the first action that a financial institution must take when it receives a garnishment order, which is to determine whether the order was obtained by the United States. In most cases, garnishment orders obtained by the United States will be readily identifiable by the caption on the first page of the order, which will read "United States of America," or "United States," or "U.S." In some cases, however, this will not be the case. Accordingly, financial institutions must also check to see whether the order is accompanied by a Notice of Garnishment by the United States, as set forth in Appendix B. Financial institutions may rely on this two-step test to determine if an order was obtained by the United States. For orders obtained by the United States, the financial institution would follow its otherwise customary procedures for handling the order. For all other orders, the financial institutions would be required to follow the procedures in sections 212.5 and 212.6.

Section 212.5

Proposed section 212.5 outlines the account review a financial institution must conduct if it has determined, pursuant to section 212.4, that a garnishment order was not obtained by the United States. In such cases, a financial institution must review the history of the account being garnished to determine if a benefit payment was deposited into the account during the lookback period. If no benefit payments were deposited to the account during the lookback period, then the financial institution would follow its otherwise customary procedures for handling the order. If a benefit payment was deposited into the account during the lookback period, then the financial institution must follow the procedures set forth in section 212.6.

Proposed section 212.5(d) lists factors that are not relevant to a financial institution's account review. The commingling of exempt and nonexempt funds in the account is not relevant to the account review, and neither is the existence of a co-owner on the account. Similarly, the fact that benefit payments to multiple beneficiaries may have been deposited to an account during the lookback period is not relevant, as could occur if an individual receives payments on behalf of several beneficiaries. Finally, any instructions or information in a garnishment order are not relevant, including information about the nature of the debt or obligation underlying the order, such as alimony or child support obligations.

Section 212.5(e) makes it clear that financial institutions must perform the account review before taking any action related to the garnishment order that may affect funds in an account. Section 212.5(f) requires a separate account review for each account against which a garnishment order has been issued, even if an individual holds more than one account at a financial institution. For example, if an individual maintains two accounts at the same financial institution, and payments issued under two different benefit programs are directly deposited to each account, both accounts must be separately reviewed and a separate protected amount must be calculated and applied for each account.

Section 212.6

Proposed section 212.6 contains the provisions that apply if a financial institution determines that one or more benefit payments were deposited to an account during the lookback period. In such a case, the financial institution must calculate the protected amount, as defined in proposed section 212.3. A financial institution may not freeze, or otherwise restrict the account holder's access to, the protected amount. The protection against freezing triggered by the depositing of exempt funds during the lookback period is automatic. A financial institution may not require an account holder to assert any right to a garnishment exemption or take any other action prior to accessing the protected amount.

Section 212.6(c) requires the financial institution to send a notice to the account holder. The content and timing required for the notice are set forth in section 212.7.

Section 212.6(d) addresses the situation in which a financial institution receives service of the same garnishment order more than once. The financial institution must execute the account review one time upon the first service of a given garnishment order. If the same garnishment order is subsequently served again upon the financial institution, the financial institution is not required to perform another account review and is restricted from taking any action on the account. If the financial institution is subsequently served a new or different garnishment order against the same account, the financial institution must execute a new account review.

Section 212.6(e) provides that a financial institution has no continuing obligation to garnish amounts deposited or credited to the account following the date of account review, and may not take any action to freeze any amounts subsequently deposited or credited unless served a new or different garnishment order. A small number of states authorize the issuance of a "continuing" garnishment order, *i.e.,* an order requiring the garnishee to monitor, preserve and remit funds coming into the garnishee's custody on an ongoing basis. The proposed rule would operate to prohibit a financial institution that is served with a continuing garnishment from complying with the order's ongoing requirements.

Section 212.6(f) provides that a financial institution may collect a garnishment fee only against funds in the account in excess of the protected amount on the date of account review. Such a fee may be charged only if the financial institution generally imposes a fee of this nature and amount for its accounts. The fee may not be imposed only on accounts to which benefit payments are deposited.

Section 212.6(g) prohibits a financial institution from charging a garnishment

fee against a protected amount, and further prohibits a financial institution from charging or collecting such a fee after the date of account review, *i.e.,* retroactively.

Section 212.7

Proposed section 212.7(a) sets forth the content of the notice that financial institutions are required to send to account holders. The financial institution must notify the account holder that the financial institution has received a garnishment order and must briefly explain what a garnishment is. The notice must also include other information regarding the account holder's rights. Financial institutions may choose to use the model notice in Appendix A to the proposed rule, in which case they will be deemed to be in compliance with the requirements of section 212.7(a). However, use of the model notice is optional.

The financial institution must deliver the notice separately from the account holder's periodic account statement. This is to ensure that the account holder does not inadvertently disregard the notice. However, the financial institution may deliver the notice concurrently with other garnishment notices or forms required under state or local law. The notice must be sent within two business days from the date of account review. The notice must be sent in any case where a benefit payment was deposited into the account during the lookback period, even if the financial institution does not freeze any funds in the account. This could be the case where the account balance is zero.

Section 212.8

Proposed section 212.8 makes it clear that the rule is not to be interpreted as limiting any rights an individual may have under Federal law to assert an exemption from garnishment, or as altering the exempt status of funds in the account. For example, although the proposed rule does not require a financial institution to review and identify Federal benefits deposited by check to an account, those funds are protected under Federal law and the account holder may assert a claim for that protection in accordance with the procedures specified under the applicable law. In addition, it is possible that an account holder could have exempt funds on deposit in excess of the protected amount. In that case, the account holder could assert the protection available under Federal law for those funds. The proposed rule does not limit or change the protected status of those funds.

Proposed section 212.8 provides that the rule is not to be construed to invalidate any term or condition of an account agreement between a financial institution and an account holder, as long as the term or condition is not inconsistent with the proposed rule. The requirements of the proposed rule may not be changed by agreement, except in the narrow circumstance permitted under proposed section 212.10(c), *i.e.,* where an account holder expressly instructs a financial institution to use exempt funds to satisfy a garnishment order after being notified of the order and the account holder's rights. Thus, a financial institution may not require an account holder to waive any protection available under the rule, nor may it include in an account agreement terms inconsistent with the requirements of the proposed rule. However, the section 212.6(b) requirement that a financial institution ensure that the account holder has access to the protected amount would be subject to any limitation on funds availability to which the account is subject. For example, if funds on deposit are subject to a hold consistent with Regulation CC,[14] or a limitation on withdrawal applicable to a time deposit, the proposed rule would not override or affect those limitations.

Section 212.9

Proposed section 212.9 preempts any State or local government law or regulation that is inconsistent with any provision of the proposed rule. Section 212.9(b) makes it clear that such a preemption occurs only to the extent that an inconsistency between the proposed rule and state law would prevent a financial institution from complying with the requirements of the proposed rule. Some state laws, for example, may protect from garnishment funds in a bank account in an amount that exceeds the protected amount. The proposed rule does not displace or supersede such a state law requirement. Section 212.9(c) allows a state to protect funds in an account from freezing or garnishment to a greater extent than is required under the proposed rule.

Section 212.10

Proposed section 212.10 provides a safe harbor for financial institutions that comply in good faith with the rule. Thus, for example, if a financial institution made available the protected amount to an account holder in accordance with the rule, the financial institution would not be liable even if a judgment creditor were able to establish in court that funds in the account at the time the garnishment order was served were attributable to nonexempt deposits. In addition, if a financial institution performed an account review within the one business day deadline, and funds were withdrawn from the account during this time, the financial institution would not be liable to a creditor or court for failure to preserve the funds in the account, even if there was no protected amount for the account. Under proposed section 212.10(c), this protection exists for a financial institution despite the occurrence of a bona fide error or a settlement adjustment.

Proposed section 212.10(c) allows a financial institution to follow an account holder's express instruction to use an otherwise protected amount to satisfy the garnishment order. The instruction must be in writing and must be delivered after the date on which the financial institution received the garnishment order. This provision would not permit an account holder to instruct a financial institution, in advance or in a standing agreement, to use exempt funds to satisfy a garnishment order.

Section 212.11

Under proposed section 212.11, compliance with the rule will be enforced by the Federal banking agencies. Financial institutions must maintain records of account activity and actions taken in handling garnishment orders sufficient to demonstrate compliance with the rule.

Section 212.12

Proposed section 212.12 provides that the proposed rule may be amended only by a joint rulemaking issued by Treasury, SSA, VA, RRB and OPM.

Appendix A to Part 212

Appendix A sets forth proposed model language that would satisfy the notice requirements of section 212.7(a). Financial institutions are not required to use this model language. However, financial institutions that use the model notice would be deemed to be in compliance with the requirements of section 212.7(a).

Appendix B to Part 212

Appendix B contains the form of Notice of Garnishment by the United States which is referred to in section 212.4(a)(2).

[14] Regulation CC, 12 CFR part 229, is the Federal Reserve's regulation establishing rules covering the collection and return of checks by banks.

IV. Regulatory Analysis

A. Executive Order 12866

It has been determined that this rule is a significant regulatory action as defined in E.O. 12866. The Office of Management and Budget has reviewed this regulation.

B. Joint Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA) requires agencies either to provide an Initial Regulatory Flexibility Analysis with a proposed rule or to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. In accordance with section 3(a) of the RFA, the Agencies have reviewed the proposed regulation, which affects all financial institutions, regardless of size. While the Agencies believe that the proposed rule likely would not have a significant economic impact on financial institutions (5 U.S.C. 605(b)), the Agencies do not have complete data at this time to make this determination. Therefore, a joint Initial Regulatory Flexibility Analysis has been prepared in accordance with 5 U.S.C. 603. The Agencies request comment on the rule's impact on small entities. The Agencies will, if necessary, conduct a final regulatory flexibility analysis after consideration of comments received during the public comment period.

1. Reasons for Proposed Rule

As discussed above, the Agencies are publishing the proposed rule to implement statutory restrictions on the garnishment of exempt Federal benefit payments. Social Security benefits, Supplemental Security Income benefits, VA benefits, Federal Railroad retirement benefits, Federal railroad unemployment and sickness benefits, and Civil Service Retirement System benefits and Federal Employees Retirement System benefits are generally exempt under Federal law from garnishment orders. These benefits often constitute a major portion and sometimes all of an individual's income. As a result, when financial institutions receive garnishment orders and place freezes on accounts containing exempt Federal benefit payments, the recipients of these funds can face significant hardship. At the same time, financial institutions are required by law to comply with garnishment orders and may be at risk of being held in contempt of court if they fail to preserve and remit funds according to the order. In many cases a financial institution would be liable for any funds that are withdrawn by an account holder after the financial institution has received a garnishment order for the account.

Furthermore, it can be difficult for a financial institution to determine whether or the extent to which an account contains Federal benefit payments that are exempt for garnishment. If, for instance, an account contains deposits of both exempt and non-exempt funds, there may be no established accounting rules to determine the proportion of the comingled funds that should be protected from garnishment.

2. Statement of Objectives and Legal Basis

The Agencies are proposing this new rule to give force and effect to the Federal anti-garnishment statutes and to provide financial institutions with straightforward rules on the handling of garnishment orders. The rule is designed to address the hardships that recipients of Federal benefit payments are encountering when a financial institution places a freeze on an account and the difficulties that financial institutions have in determining whether funds deposited into an account are exempt from garnishment. As discussed above, the primary goals of the proposed rule are (1) to ensure that benefit recipients have access to exempt funds while garnishment orders are complied with, adjudicated, or otherwise resolved; (2) to protect financial institutions from liability when, having received a garnishment order for an account receiving Federal benefit payments, they allow the account holder access to exempt funds in the account; and (3) to establish straightforward, uniform, cost effective procedures addressing the extent to which financial institutions may, pursuant to garnishment orders, freeze or seize funds in accounts that contain Federal benefits.

3. Description and Estimate of Small Entities Affected by the Proposed Rule

The proposed rule would apply to financial institutions, including national banks, savings associations, state member banks, and Federal and state credit unions. The proposed rule would affect all financial institutions, regardless of size, that might hold an account to which Federal benefits may be directly deposited. For purposes of the RFA, a "small entity" is a national bank, savings association, State member bank, or State or Federal credit union with assets of $175 million or less. The Agencies estimate that there are 8,082 national banks, savings associations, and state member banks, of which 56% have assets equal or less than $175 million.[15] In addition, the Agencies estimate that there are 7,689 National and State credit unions of which 88% have assets equal or less than $175 million. The proposed rule would apply to all of these institutions.

4. Projected Recordkeeping, Reporting, and Other Compliance Requirements

Financial institutions currently administer and respond to garnishment orders, and already maintain records related to the actions they take in response to garnishment orders, and so the basic requirements embodied in the proposed rule do not represent new activities. Furthermore, the proposed rule would not require investments in new equipment or modification to systems. Financial institutions would, however, have new requirements under the rule. They will need to modify their garnishment operating procedures to determine whether orders are obtained by the United States and ascertain whether benefit payments were deposited to an account within 60 calendar days of receiving a garnishment order. If so, they would be required to establish a protected amount which cannot be frozen and to issue a notice to the account holder disclosing facts and information about the garnishment order.

Financial institutions would be able to utilize existing systems to comply with the rule. As discussed above in the Overview of this proposed rule, Treasury will encode an "X" in position 20 of the "Company Name" Field of the Batch Header Record for each Agency exempt benefit Automated Clearing House (ACH) payment. This encoding, along with the current practice of encoding a "2" in the "Originator Status Code" Field in the Batch Header Record to designate payments originated from the Federal government, will allow financial institutions to readily identify Federal exempt payments through either manual or systems inspection without additional resources or equipment. In addition, the Agencies will publish a list of the unique "Entry Detail Description" Fields in the Batch Header Record that can be used to identify exempt benefit payments.

Given the existing burden under law to handle garnishment orders, coupled with the simplicity, uniformity, and certainty of the requirement to establish a protected amount under the proposed rule, the Agencies conclude that

[15] *See* FDIC Bank Find (Number of Small Banks), *http://www2.fdic.gov/idasp/main_bankfind.asp* (last visited Nov. 19, 2009); *see also* NCUA, Credit Union Data (Number of Small Credit Unions), *http://webapps.ncua.gov/customquery/* (last visited Nov. 19, 2009).

modifications to financial institution operating procedures represent a one-time administrative change that would require new internal documentation and employee training but would not result in substantive additional on-going activities. The requirement to issue a notice entails mailing a one-page standard document and the Agencies conclude that this requirement entails minimal resources.

Therefore, the Agencies believe that any costs incurred as a result of the proposed rule will be minimal. Furthermore, the Agencies believe that financial institutions will benefit from the clarity and uniformity the proposed rule will bring to the handling of garnishment orders, and from the safe harbor protections against liability. In addition, the rule should result in fewer customer service issues arising from account freezes and garnishment orders generally. Finally, the Agencies are aware that, for a variety of reasons, some financial institutions already attempt to review account histories and issue notices to account holders upon receipt of a garnishment order. To the extent that these activities already occur, the proposed rule should have little or no impact.

The Agencies seek information and comment on any costs, compliance requirements, or changes in operating procedures arising from the application of the proposed rule and the extent to which those costs, requirements, or changes are in addition to or different from those arising from current processes in effect when a court ordered garnishment is served. The Agencies invite comment and data on the size of the incremental burden on small financial institutions in instituting procedures not currently part of the institution's practices. In addition, the Agencies are interested in knowing whether particular aspects of the proposed rule would be especially costly or burdensome. We also invite comment on Treasury's plans to encode its ACH entries with a garnishment identifier in the "Company Name" Field and to publish a list of unique "Entry Detail Description" Fields to facilitate the identification of exempt Federal benefit payments.

The Agencies anticipate contacting trade groups representing participants that qualify as small entities and encouraging them to provide comments during the comment period to ascertain, among other things the costs imposed on the regulated small entities.

5. Identification of Duplicative, Overlapping, or Conflicting Federal Rules

The Agencies reviewed current law and have constructed the proposed rule so that no Federal statutes or rules would overlap or conflict with the proposed rule. The Agencies seek comment and information about any such statutes or rules, as well as any other State, local, or industry rules or policies that require a financial institution to implement business practices that would conflict with the requirements of the proposed rule.

6. Discussion of Significant Alternatives

The proposed rule would apply to all financial institutions that maintain accounts to which Federal benefit payments may be deposited. One approach to minimizing the burden on small entities would be to provide a specific exemption for small institutions. The Agencies propose that the requirements in this rule be applicable to all entities regardless of size, because an exemption for small entities would diminish the usefulness of the policies and procedures laid out to ensure that all benefit recipients nationwide have access to a certain amount of lifeline funds. An exemption might result in the continuation of the current practice of account freezes for some recipients.

On behalf of the Agencies, Treasury has worked over the past two years with major trade associations and various Federal regulators to devise a balanced, uniform rule that will resolve the problems surrounding garnishment and Federal benefits. In consultation with these organizations, the Agencies have attempted to minimize burden by proposing a single rule that would apply to all types of exempt Federal benefit payments and establish a consistent set of practices for all financial institutions to follow. In addition, the Agencies have attempted to ensure that financial institutions will not incur legal liability including in the proposed rule a safe harbor provision and an express preemption of inconsistent state law. The result should be a straightforward rule that can be implemented in a cost-effective manner. The Agencies welcome comments on any significant alternatives to the proposed rule.

C. Executive Order 13132 Determination

Executive Order 13132 outlines fundamental principles of Federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these Federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

In the Agencies' view, the proposed rule may have Federalism implications, because it has direct, although not substantial, effects on the States, the relationship between the national government and states, or on the distribution of power and responsibilities among various levels of government. The provision in the rule (§ 212.4) where the Agencies establish a process for financial institutions' treatment of accounts upon the receipt of a garnishment order could potentially conflict with State garnishment laws prescribing a formula for financial institutions to pay such claims.

The proposed rule's central provision requiring a financial institution to establish a protected amount will affect only a very small percentage of all garnishment orders issued by State courts, since in the vast majority of cases an account will not contain an exempt Federal benefit payment. Moreover, states may choose to provide stronger protections against garnishment, and the proposed regulation will only override state law to the minimum extent necessary to protect Federal benefits payments from garnishment.

Under 42 U.S.C. 407(a) and 42 U.S.C. 1383(d)(1), Federal Old-Age, Survivors, and Disability Insurance benefits and Supplemental Security Income payments are generally exempt from garnishment. 42 U.S.C. 405(a) provides the Commissioner of Social Security with the authority to make rules and regulations concerning Federal Old-Age, Survivors, and Disability Insurance benefits. The Social Security Act does not require State law to apply in the event of conflict between State and Federal law.

Under 38 U.S.C. 5301(a), benefits administered by VA are generally exempt from garnishment. 38 U.S.C. 501(a) provides the Secretary of Veterans Affairs with the authority to make rules and regulations concerning VA benefits. The statutes governing VA benefits do not require State law to apply in the event of conflict between State and Federal law.

Under 45 U.S.C. 231m(a), Federal railroad retirement benefits are generally exempt from garnishment. 45 U.S.C. 231f(b)(5) provides the RRB with rulemaking authority over issues rising from the administration of Federal Railroad retirement benefits. The Railroad Retirement Act of 1974 does not require State law to apply in the event of conflict between State and Federal law.

Under 45 U.S.C. 352(e), Federal railroad unemployment and sickness benefits are generally exempt from garnishment. 45 U.S.C. 362(1) provides the RRB with rulemaking authority over issues rising from the administration of Federal railroad unemployment and sickness benefits. The Railroad Unemployment Insurance Act does not require State law to apply in the event of a conflict between State and Federal law.

Under 5 U.S.C. 8346, for the Civil Service Retirement System (CSRS) and under 5 U.S.C. 8470, for the Federal Employees Retirement Systems (FERS), Federal retirement benefits are generally exempt from garnishment. 5 U.S.C. 8347 and 5 U.S.C. 8461, respectively, provide the Director of OPM with the authority to make rules and regulations concerning CSRS and FERS benefits. OPM benefits statutes do not require State law to apply in the event of conflict between State and Federal law.

In accordance with the principles of Federalism outlined in Executive Order 13132, the Agencies consulted with State officials on issues addressed in this rulemaking. Specifically, the Agencies sought perspective on those matters where Federalism implications could potentially conflict with State garnishment laws. The proposed rule establishes certain processes that provide a financial institution protection from liability when a Federal benefit payment exempt from garnishment is directly deposited into an account and the financial institution provides a certain amount of lifeline funds to the benefit recipient.

D. Unfunded Mandates Reform Act of 1995 Determinations

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (Unfunded Mandates Act) requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The Agencies have determined that this proposed rule will not result in expenditures by state, local, and tribal governments, or by the private sector, of $100 million or more. Accordingly, the Agencies have not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

E. Plain Language

In 1998, the President issued a memorandum directing each agency in the Executive branch to use plain language for all new proposed and final rulemaking documents issued on or after January 1, 1999. The Agencies specifically invite your comments on how to make this proposal easier to understand. For example:

- Have we organized the material to suit your needs? If not, how could this material be better organized?
- Are the requirements in the proposed rule clearly stated? If not, how could the rule be more clearly stated?
- Does the proposed rule contain language or jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand? If so, what changes to the format would make them easier to understand?
- What else could we do to make the rule easier to understand?

F. Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Office of the Deputy Assistant Secretary, Fiscal Operations and Policy, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Room 2112, Washington, DC 20220. Comments on the collection of information must be received by June 18, 2010. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Agencies, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in these proposed regulations are found in §§ 212.5 and 212.9.

Estimated total annual reporting burden: 125,000 hours.

Estimated average annual burden per respondent: 8 hours.

Estimated number of respondents: 15,771.

Estimated frequency of responses: As needed.

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 the Office of Management and Budget.

List of Subjects

5 CFR Part 831

Administrative practice and procedure, alimony, benefit payments, claims, disability benefits, exempt payments, financial institutions, firefighters, garnishment, government employees, income taxes, intergovernmental relations, law enforcement officers, pensions, preemption, reporting and recordkeeping requirements, retirement.

5 CFR Part 841

Administrative practice and procedure, air traffic controllers, benefit payments, claims, disability benefits, exempt payments, financial institutions, firefighters, garnishment, government employees, income taxes, intergovernmental relations, law enforcement officers, pensions, preemption, retirement.

20 CFR Part 350

Alimony, benefit payments, child support, exempt payments, financial institutions, garnishment, preemption, railroad retirement, railroad unemployment insurance, recordkeeping.

20 CFR Part 404

Administrative practice and procedure, aged, alimony, benefit

payments, blind, disability benefits, exempt payments, financial institutions, garnishment, government employees, income taxes, insurance, investigations, old-age, preemption, Survivors and Disability Insurance, penalties, railroad retirement, reporting and recordkeeping requirements, Social Security, travel and transportation expenses, treaties, veterans, vocational rehabilitation.

20 CFR Part 416

Administrative practice and procedure, alcoholism, benefit payments, drug abuse, exempt payments, financial institutions, garnishment, investigations, Medicaid, penalties, preemption, reporting and recordkeeping requirements, Supplemental Security Income (SSI), travel and transportation expenses, vocational rehabilitation.

31 CFR Part 212

Benefit payments, exempt payments, financial institutions, garnishment, preemption, recordkeeping.

38 CFR Part 1

Administrative practice and procedure, archives and records, benefit payments, cemeteries, claims, courts, crime, flags, exempt payments, financial institutions, freedom of information, garnishment, government contracts, government employees, government property, infants and children, inventions and patents, parking, penalties, preemption, privacy, reporting and recordkeeping requirements, seals and insignia, security measures, wages.

Department of the Treasury, Fiscal Service (Treasury)

Authority and Issuance

For the reasons set forth in the preamble, Treasury proposes to add a new part 212 to Title 31 of the Code of Federal Regulations, to read as follows:

PART 212—GARNISHMENT OF ACCOUNTS CONTAINING FEDERAL BENEFIT PAYMENTS

Sec.

Authority: 5 U.S.C. 8346; 5 U.S.C. 8470; 5 U.S.C. 1103; 31 U.S.C. 321; 31 U.S.C. 3321; 31 U.S.C. 3332; 38 U.S.C. 5301(a); 38 U.S.C. 501(a); 42 U.S.C. 405(a); 42 U.S.C. 407; 42 U.S.C. 659; 42 U.S.C. 1383(d)(1); 45 U.S.C. 231f(b); 45 U.S.C. 231m; 45 U.S.C. 352(e); 45 U.S.C. 362(1).

§ 212.1 Purpose.

The purpose of this part is to implement statutory provisions that protect Federal benefits from garnishment by establishing procedures that financial institutions must follow when a garnishment order is received for an account into which Federal benefit payments have been directly deposited.

§ 212.2 Scope.

This part applies to:

(a) *Entities.* All financial institutions, as defined in § 212.3.

(b) *Funds.* Benefit payments issued under the following Federal programs:

(1) SSA benefit payments protected under 42 U.S.C. 407 and 42 U.S.C. 1383(d)(1);

(2) VA benefit payments protected under 38 U.S.C. 5301(a);

(3) RRB benefit payments protected under 45 U.S.C. 231m(a) and 45 U.S.C. 352(e); and

(4) OPM benefit payments protected under 5 U.S.C. 8346 and 5 U.S.C. 8470.

§ 212.3 Definitions.

For the purposes of this part, the following definitions apply.

Account means an account at a financial institution to which benefit payments can be delivered by direct deposit.

Account review means the process of examining deposits in an account to determine if a benefit agency has deposited a benefit payment into the account during the lookback period.

Benefit agency means the Social Security Administration (SSA), the Department of Veterans Affairs (VA), the Office of Personnel Management (OPM), or the Railroad Retirement Board (RRB).

Benefit payment means a direct deposit payment made by a benefit agency to a natural person or to a representative payee receiving payments on behalf of a natural person under a Federal program listed in § 212.2(b).

Federal banking agency means the Federal Deposit Insurance Corporation, the Board of Governors of the Federal Reserve System, the Office of the Comptroller of the Currency, the Office of Thrift Supervision, or the National Credit Union Administration.

Financial institution means a bank, savings association, credit union, or other entity chartered under Federal or State law to engage in the business of banking.

Freeze or *account freeze* means an action by a financial institution to seize, withhold, or preserve funds, or to otherwise prevent an account holder from drawing on or transacting against funds in an account, in response to a garnishment order.

Garnish or *garnishment* means execution, levy, attachment, or other legal process to enforce a money judgment.

Garnishment fee means any service or legal processing fee, charged by a financial institution to an account holder, for processing a garnishment order or any associated withholding or release of funds.

Garnishment order or *order* means a writ, order, notice, summons, or similar written instruction issued by a court to effect a garnishment.

Lookback period means the 60-calendar-day period preceding the date on which a financial institution is served a garnishment order.

Protected amount means the lesser of the sum of all benefit payments deposited to an account during the lookback period or the balance in an account on the date of account review.

State means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, or the United States Virgin Islands.

§ 212.4 Initial action upon receipt of a garnishment order.

(a) *Examination for orders obtained by the United States.* Prior to taking any other action related to a garnishment order issued against an account, and no later than one business day following receipt of the order, a financial institution shall examine the order to determine if it was obtained by the United States. A garnishment order shall conclusively be considered to have been obtained by the United States if:

(1) The plaintiff named in the caption on the front page of the order is "United States of America," or "United States," or "U.S."; or

(2) The order is served on the financial institution accompanied by a Notice of Garnishment by the United States, as set forth in Appendix B.

(b) *United States obtained the order.* If an order meets either of the criteria set forth in § 212.4(a)(1) or (2), then the financial institution shall follow its otherwise customary procedures for handling the garnishment order and

shall not follow the procedures in § 212.5 and § 212.6.

(c) *United States did not obtain the order.* If an order does not meet either of the criteria set forth in § 212.4(a)(1) or (2), then the financial institution shall follow the procedures in § 212.5 and § 212.6.

§ 212.5 Account review.

(a) *Review for benefit payment.* No later than one business day following receipt of a garnishment order issued against an account, a financial institution shall perform an account review.

(b) *No benefit payment deposited during lookback period.* If the account review shows that a benefit agency did not deposit a benefit payment into the account during the lookback period, then the financial institution shall follow its otherwise customary procedures for handling the garnishment order and shall not follow the procedures in § 212.6.

(c) *Benefit payment deposited during lookback period.* If the account review shows that a benefit agency deposited a benefit payment into the account during the lookback period, then the financial institution shall follow the procedures in § 212.6.

(d) *Uniform application of account review.* The financial institution shall perform an account review without consideration for any other attributes of the account or the garnishment order, including but not limited to:

(1) The presence of other funds, from whatever source, that may be commingled in the account with funds from a benefit payment;

(2) The existence of a co-owner on the account;

(3) The existence of benefit payments to multiple beneficiaries, and/or under multiple programs, deposited in the account;

(4) The balance in the account, provided the balance is above zero dollars on the date of account review;

(5) Instructions to the contrary in the garnishment order; or

(6) The nature of the debt or obligation underlying the garnishment order, including whether the order seeks to collect alimony or child support obligations.

(e) *Priority of Account Review.* The financial institution shall perform the account review prior to taking any other actions related to the garnishment order that may affect funds in the account.

(f) *Separate account reviews.* The financial institution shall perform the account review separately for each account in the name of an account holder against whom a garnishment order has been issued.

§ 212.6 Rules and procedures to protect benefits.

The following provisions apply if an account review shows that a benefit agency deposited a benefit payment into an account during the lookback period.

(a) *Protected amount.* The financial institution shall immediately calculate and establish the protected amount for an account. The financial institution shall ensure that the account holder has access to the protected amount, which the financial institution shall not freeze in response to the garnishment order. An account holder shall have no requirement to assert any right of garnishment exemption prior to accessing the protected amount.

(b) *Funds in excess of the protected amount.* For any funds in an account in excess of the protected amount, the financial institution shall follow its otherwise customary procedures for handling garnishment orders, including the freezing of funds, but consistent with paragraphs (e) and (f) of this section.

(c) *Notice.* The financial institution shall issue a notice to the account holder, in accordance with § 212.7.

(d) *One-time account review process.* The financial institution shall perform the account review only one time upon the first service of a given garnishment order. The financial institution shall not repeat the account review or take any other action related to the garnishment order if the same garnishment order is subsequently served again upon the financial institution. If the financial institution is subsequently served a new or different garnishment order against the same account holder, the financial institution shall perform a separate and new account review.

(e) *No continuing or periodic garnishment responsibilities.* The financial institution shall have no continuing obligation to garnish amounts deposited or credited to the account following the date of account review, and shall take no action to freeze any funds subsequently deposited or credited unless the institution is served with a new or different garnishment order, consistent with the requirements of this part.

(f) *Permissible garnishment fee.* The financial institution may collect a garnishment fee only against funds in the account in excess of the protected amount on the date of account review, provided that the nature and amount of the fee is customary for the financial institution's accounts generally and is not specific to accounts with benefit payments.

(g) *Impermissible garnishment fee.* The financial institution may not charge or collect a garnishment fee against a protected amount, and may not charge or collect a garnishment fee after the date of account review.

§ 212.7 Notice to the account holder.

A financial institution shall issue the notice required by § 212.6(c) in accordance with the following provisions.

(a) *Notice content.* The financial institution shall notify the account holder of the following facts and events in readily understandable language.

(1) The financial institution's receipt of a garnishment order against the account holder.

(2) The date on which the garnishment order was served.

(3) A succinct explanation of garnishment orders.

(4) The financial institution's requirement under Federal regulation to ensure that account balances up to the protected amount specified in § 212.3 are protected and made available to the account holder if a benefit agency deposited a benefit payment into the account in the last 60 calendar days.

(5) The protected amount, if any, established by the financial institution.

(6) The financial institution's potential requirement pursuant to other law to freeze other amounts in the account to satisfy the garnishment order.

(7) An exemplary list of Federal, State, and other benefits generally exempt from garnishment.

(8) The account holder's right to assert a further garnishment exemption for amounts above the protected amount, by completing exemption claim forms, contacting the court of jurisdiction, or contacting the judgment creditor, as customarily applicable for a given jurisdiction.

(9) Means of contacting the judgment creditor.

(10) Means of contacting the court of jurisdiction.

(11) Means of contacting the financial institution.

(b) *Notice delivery.* The financial institution shall not include the notice with the delivery of a periodic account statement, but must deliver it under separate cover. The financial institution may deliver the notice concurrently with other garnishment notices or forms pursuant to State or local government law.

(c) *Notice timing.* The financial institution shall send the notice to the account holder within 2 business days from the date of account review.

(d) *Notice requirement.* The financial institution shall send the notice in all cases where a benefit agency deposited

a benefit payment into the account during the lookback period, including cases where the financial institution does not freeze any funds in the account.

§ 212.8 Other rights and authorities.

(a) *Exempt status.* Nothing in this part shall be construed to limit an individual's right under Federal law to assert an exemption from garnishment for funds in excess of the protected amount, or to alter the exempt status of funds that may be protected from garnishment under Federal law.

(b) *Account agreements.* Nothing in this part shall be construed to invalidate any term or condition of an account agreement between a financial institution and an account holder that is not inconsistent with this part.

§ 212.9 Preemption of state law.

(a) *Inconsistent law preempted.* To the extent that any state or local government law or regulation is inconsistent with a provision of this part, it is hereby preempted.

(b) *Consistent law not preempted.* Nothing in this part shall be construed to preempt any state or local government law or regulation in the field of garnishment that is not inconsistent with this part, including but not limited to procedures to determine the disposition of funds in excess of a protected amount.

(c) *Higher protected amount.* Notwithstanding any provision of this part, a state may by law or regulation protect funds in an account from freezing or garnishment at a higher protected amount than is required under this part, provided that such law or regulation is not inconsistent with any other provision of this part.

§ 212.10 Safe harbor.

(a) *Protection during examination and review.* A financial institution that complies in good faith with this part shall not be liable to a judgment creditor for any protected amounts, to an account holder for any frozen amounts, or for any penalties under state law, contempt of court, civil procedure, or other law for failing to honor a garnishment order for account activity during the one business day following the financial institution's receipt of a garnishment order.

(b) *General protection for financial institutions.* A financial institution that complies in good faith with this part shall not be liable to a judgment creditor for any protected amounts, to an account holder for any frozen amounts, or for any penalties under state law, contempt of court, civil procedure, or other law for failing to honor a garnishment order in cases where

(1) A benefit agency has deposited a benefit payment into an account during the lookback period or

(2) The financial institution has determined that an order was obtained by the United States by following the procedures in § 212.4(a)(1) and (2).

(c) *Protection for financial institution from other potential liabilities.* A financial institution that complies in good faith with this part shall not liable for:

(1) Bona fide errors that occur despite reasonable procedures maintained by the financial institution to prevent such errors in complying with the provisions of this part;

(2) Customary clearing and settlement adjustments that affect the balance in an account, including a protected amount, such as deposit reversals caused by the return of unpaid items; or

(3) Honoring an account holder's express written instructions, received by the financial institution following the date on which it has been served a particular garnishment order, to use an otherwise protected amount to satisfy the garnishment order.

§ 212.11 Compliance and record retention.

(a) *Enforcement.* Federal banking agencies will enforce compliance with this part.

(b) *Record retention.* A financial institution shall maintain records of account activity and actions taken in response to garnishment orders sufficient to demonstrate compliance with this part.

§ 212.12 Amendment of this part.

This part may be amended only by a rulemaking issued jointly by Treasury and all of the benefit agencies.

Appendix A to Part 212—Model Notice to Account Holder

A financial institution may use the following model notice to meet the requirements of § 212.7(a). Although use of this model is not required, a financial institution using it properly is deemed to be in compliance with § 212.7(a).

Notice of Garnishment

On [insert date of garnishment order receipt], [insert financial institution name] received an order of garnishment to freeze or remove funds from your account.

If you owe money to a creditor, garnishment is the legal process that allows your creditor to obtain a court order directing your financial institution to freeze or turn over funds in your account to pay the debt you owe the creditor.

However, you have certain protections from garnishment if the funds in your account include Federal benefit payments such as Social Security benefits, Supplemental Security Income benefits, benefits administered by the Department of Veterans Affairs, Railroad retirement benefits, Railroad Unemployment Insurance benefits, Civil Service Retirement System benefits or Federal Employees Retirement System benefits. We are required by Federal regulation to review your account and determine whether any such benefits were directly deposited to your account within 60 calendar days preceding our receipt of the garnishment order. If so, the sum of all such benefits (or your full account balance, if it is less than that amount) cannot be turned over to your creditor or frozen, and you may withdraw or use these funds as you normally would.

If your account contains funds in excess of the sum of the benefits directly deposited during the 60-day period, those funds are subject to the garnishment order and may be frozen or turned over to your creditors.

Protected Funds in Your Account

We have determined that one or more Federal benefit payments were deposited to your account within 60 calendar days preceding our receipt of the garnishment order. The balance in your account when we conducted our review was $____. Of this amount, [insert protected amount] is protected under Federal law from garnishment or freezing. You may continue to access these funds as usual.

[Additional Funds in Your Account

Your account also contains additional funds. We have placed a hold on these funds and may turn them over to your creditor as directed by the garnishment order. If you believe that some or all of these additional funds are also Federal benefit payments, you may have additional rights to protect these funds. In addition, you may have rights to protect other funds in your account from garnishment, such as public assistance (welfare), disability benefits, workers' compensation benefits, and pension benefits.

You can make a claim for these rights by (insert, as applicable and required for the jurisdiction, a standard instruction or a reference to the jurisdiction's notice for completing an exemption claim form, process for contacting the court, or process for contacting the judgment creditor).]

Contact Information

The creditor that obtained the garnishment order against your account is [insert name] and may be contracted at [insert phone number].

The court that issued the garnishment order is [insert name] and their general information line is [insert phone number].

You may call us at [insert phone number].

Appendix B to Part 212—Form of Notice of Garnishment by the United States

Notice of Garnishment by the United States

The attached garnishment order was obtained by the United States.

Accordingly, the garnishee is hereby notified that the procedures established under 31 CFR Part 212 for identifying and

protecting Federal benefits deposited to accounts at financial institutions do not apply to this garnishment order.

The garnishee should comply with the terms of this order, including instructions for withholding and retaining any funds deposited to any account(s) covered by this order, pending further order of the court.

I, the undersigned, certify that my organization is part of the United States, as defined in 28 U.S.C. 3002(15), and has authority to conduct litigation for the collection of debts on behalf of the United States.

Signature: _____
Title: _____
Organization: _____
Date: _____

Social Security Administration

20 CFR Parts 404 and 416

Authority and Issuance

For the reasons set forth in the preamble, the Social Security Administration proposes to amend Parts 404 and 416 of Title 20 of the Code of Federal Regulations as follows:

PART 404—FEDERAL OLD–AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart S—Payment Procedures

1. The authority citation for subpart S of Part 404 continues to read as follows:

Authority: Secs. 205(a) and (n), 207, 702(a)(5) and 708(a) of the Social Security Act (42 U.S.C. 405(a) and (n), 407, 902(a)(5) and 909(a)).

2. Add § 404.1821 to read as follows:

§ 404.1821 Garnishment of Payments After Disbursement.

(a) Payments that are covered by section 207 of the Social Security Act and made by direct deposit are subject to 31 CFR Part 212, Garnishment of Accounts Containing Federal Benefit Payments.

(b) This section may be amended only by a rulemaking issued jointly by the Department of Treasury, the Social Security Administration, the Department of Veterans Affairs, the Railroad Retirement Board, and the Office of Personnel Management.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart E—Payment of Benefits, Overpayments, and Underpayments

3. The authority citation for subpart E of Part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1147, 1601, 1602, 1611(c) and (e), and 1631(a)–(d) and (g) of the Social Security Act (42 U.S.C. 902(a)(5), 1320b–17, 1381, 1381a, 1382(c) and (e), and 1383(a)–(d) and (g)); 31 U.S.C. 3720A.

4. Add § 416.534 to read as follows:

§ 416.534 Garnishment of Payments After Disbursement.

(a) Payments that are covered by section 1631(d)(1) of the Social Security Act and made by direct deposit are subject to 31 CFR Part 212, Garnishment of Accounts Containing Federal Benefit Payments.

(b) This section may be amended only by a rulemaking issued jointly by the Department of Treasury, the Social Security Administration, the Department of Veterans Affairs, the Railroad Retirement Board, and the Office of Personnel Management.

Department of Veterans Affairs

Authority and Issuance

For the reasons set forth in the preamble, the Department of Veterans Affairs proposes to amend Part 1 of Title 38 of the Code of Federal Regulations as follows:

PART 1—GENERAL PROVISIONS

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

Authority: 38 U.S.C. 501(a), and as noted in specific sections.

2. Add § 1.1000 and a new undesignated center heading preceding the section to read as follows:

Procedures for Financial Institutions Regarding Garnishment of Benefit Payments After Disbursement

§ 1.1000 Garnishment of payments after disbursement.

(a) Payments of benefits due under any law administered by the Secretary that are protected by 38 U.S.C. 5301(a) and made by direct deposit to a financial institution are subject to 31 CFR part 212, Garnishment of Accounts Containing Federal Benefit Payments.

(b) This section may be amended only by a rulemaking issued jointly by the Department of the Treasury, the Social Security Administration, the Department of Veterans Affairs, the Railroad Retirement Board and the Office of Personnel Management.

Railroad Retirement Board

Authority and Issuance

For the reasons set forth in the preamble, the Railroad Retirement Board proposes to amend Part 350 of Title 20 of the Code of Federal Regulations as follows:

PART 350—GARNISHMENT OF BENEFITS PAID UNDER THE RAILROAD RETIREMENT ACT, THE RAILROAD UNEMPLOYMENT INSURANCE ACT, AND UNDER ANY OTHER ACT ADMINISTERED BY THE BOARD

1. Revise the authority citation to read as follows:

Authority: 15 U.S.C. 1673(b)(2); 42 U.S.C. 659; and 45 U.S.C. 231f(b)(5), 231m, 352(e), and 362(l).

2. Add a new § 350.6 to read as follows:

§ 350.6. Garnishment of payments after disbursement.

Payments that are covered by 45 U.S.C. 231m or 45 U.S.C. 352(e) and that are made by direct deposit are subject to 31 CFR part 212, Garnishment of Accounts Containing Federal Benefit Payments. This section may be amended only by a rulemaking issued jointly by the Department of the Treasury, the Social Security Administration, the Department of Veterans Affairs, the Railroad Retirement Board and the Office of Personnel Management.

Office of Personnel Management

Authority and Issuance

For the reasons set forth in the preamble, the Office of Personnel Management proposes to amend parts 831 and 841 of Title 5 of the Code of Federal Regulations as follows:

PART 831—RETIREMENT

1. The authority citation for part 831 is revised to read as follows:

Authority: Sec. 831.2203 also issued under section 7001(a)(4) of Pub. L. 101–508, 104 Stat. 1388–328; Secs. 831.115 and 831.116 also issued under 5 U.S.C. 8346(a).

2. Add a new § 831.115 to Subpart A to read as follows:

§ 831.115 Garnishment of CSRS payments.

CSRS payments are not subject to execution, levy, attachment, garnishment or other legal process except as expressly provided by Federal law.

3. Add a new section 831.116 to read as follows:

§ 831.116 Garnishment of payments after disbursement.

(a) Payments that are covered by 5 U.S.C. 8346(a) and made by direct deposit are subject to 31 CFR part 212, Garnishment of Accounts Containing Federal Benefit Payments.

(b) This section may be amended only by a rulemaking issued jointly by the Department of the Treasury, the Social

Security Administration, the Department of Veterans Affairs, the Railroad Retirement Board and the Office of Personnel Management.

PART 841—FEDERAL EMPLOYEES RETIREMENT SYSTEM—GENERAL ADMINISTRATION

1. The authority citation for part 841 is revised to read as follows:

Authority: 5 U.S.C. 8461; Sec. 841.108 also issued under 5 U.S.C. 552a; subpart D also issued under 5 U.S.C. 8423; Sec. 841.504 also issued under 5 U.S.C. 8422; Sec. 841.507 also issued under section 505 of Pub. L. 99–335; subpart J also issued under 5 U.S.C. 8469; Sec. 841.506 also issued under 5 U.S.C. 7701(b)(2); Sec. 841.508 also issued under section 505 of Pub. L. 99–335; Sec. 841.604 also issued under Title II, Pub. L. 106–265, 114 Stat. 780; Secs. 841.110 and 841.111 also issued under 5 U.S.C. 8470(a).

2. Add new § 841.110 to read as follows:

§ 841.110 Garnishment of FERS payments.

FERS payments are not subject to execution, levy, attachment, garnishment or other legal process except as expressly provided by Federal law.

3. Add a new § 841.111 to read as follows:

§ 841.111 Garnishment of payments after disbursement.

(a) Payments that are covered by 5 U.S.C. 8470(a) and made by direct deposit are subject to 31 CFR part 212, Garnishment of Accounts Containing Federal Benefit Payments.

(b) This section may be amended only by a rulemaking issued jointly by the Department of the Treasury, the Social Security Administration, the Department of Veterans Affairs, the Railroad Retirement Board and the Office of Personnel Management.

By the Department of the Treasury.

Richard L. Gregg,

Acting Fiscal Assistant Secretary.

By the Social Security Administration.

Michael J. Astrue,

Commissioner of Social Security.

Dated: April 9, 2010.

By the Department of Veterans Affairs.

John R. Gingrich,

Chief of Staff.

Dated: April 6, 2010.

By the Railroad Retirement Board.

Beatrice Ezerski,

Secretary to the Board.

By the Office of Personnel Management.

John Berry,

Director.

[FR Doc. 2010–8899 Filed 4–14–10; 4:15 pm]

BILLING CODE 4810–25–P

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 890 and 892

RIN 3206–AL95

Federal Employees Health Benefits Program; Miscellaneous Changes

AGENCY: U.S. Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The U.S. Office of Personnel Management is proposing to amend its regulations to provide for continuation of Federal Employees Health Benefits (FEHB) coverage for certain former Senate Restaurant employees who transferred to employment with a private contractor. We are also proposing to change the annual FEHB Program Open Season from the Monday of the second full workweek in November through the Monday of the second full workweek in December, to November 1st through November 30th of each year. We are also adding a new opportunity for eligible employees to enroll in the FEHB Program or to change enrollment from self only to self and family under the Children's Health Insurance Program Reauthorization Act of 2009. Finally, we are proposing to allow FEHB plans to offer three options, without the requirement that one of the options be a high deductible health plan.

DATES: OPM must receive comments on or before June 18, 2010.

ADDRESSES: Send written comments to Ronald L. Brown, Healthy Policy, Planning & Policy Analysis, Office of Personnel Management, 1900 E Street NW., Washington, DC 20415–3666; or deliver to OPM, Room 3425, 1900 E Street NW., Washington, DC or FAX to (202) 606–0633.

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 Regulation Identifier Number (RIN) for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Ron Brown, (202) 606–0004, or e-mail at *ronald.brown@opm.gov.*

SUPPLEMENTARY INFORMATION:

Background

Senate Restaurants Employees

Public Law 110–279, enacted July 17, 2008, provides for certain Federal employee benefits to be continued for certain employees of the Senate Restaurants after the operations of the Senate Restaurants are contracted to be performed by a private business concern. The law provides that a Senate Restaurants employee who was an employee of the Architect of the Capitol on the date of enactment and who accepted employment by the private business concern as part of the transition, may elect to continue Federal benefits during continuous employment with the business concern. We are proposing to conform the regulations to these provisions of Public Law 110–279.

Change in Dates of Open Season

The current regulations provide for the FEHB Program Open Season to be held from the Monday of the second full workweek in November through the Monday of the second full workweek in December of each year. We are revising the regulations to change these dates to the month of November. Therefore, beginning in 2010, the Open Season dates will be November 1st through November 30th of each year. This will simplify the annual announcement of the time period for Open Season and allow agencies and employees to better plan for the enrollment opportunity since they will know well in advance when it will occur each year.

New Enrollment Opportunities

Public Law 111–3, the Children's Health Insurance Program (CHIP) Reauthorization Act of 2009 (the Act), enacted on February 4, 2009, allows States to subsidize health insurance premium payments for certain low-income children who have access to qualified employer-sponsored health insurance coverage. FEHB-eligible enrollees who meet the criteria for child health assistance are eligible to receive State premium subsidy assistance payments to help them pay for their FEHB plan premiums. Current FEHB Program regulations already allow an eligible enrollee who loses coverage under the FEHB Program or another group health plan, including loss of eligibility or assistance under Medicaid or CHIP, to enroll or change enrollment from self only to self and family within the period beginning 31 days before and ending 60 days after the date of loss of coverage. The Act provides new opportunities for eligible employees to enroll in the FEHB Program or to change enrollment from self only to self and family when the employee or an eligible family member becomes eligible for premium assistance under CHIP. Employees must request the change in enrollment within 60 days after the date the employee or eligible family member is determined to be eligible for assistance. Employees may make these

enrollment changes regardless of whether they are covered under premium conversion (pay premiums with pre-tax dollars).

Change in Options Offered

The current regulations state that an FEHB plan shall not have more than two options and a high deductible health plan. We are proposing to revise the regulations to allow employee organization plans and health maintenance organizations to both offer two options and a high deductible health plan or to offer three options, without the requirement that one of the options be a high deductible health plan. This will provide for more flexibility in contracting with health plans for modern types of benefits.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation only affects health insurance benefits of Federal employees and annuitants.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles, and responsibilities of State, local, or Tribal governments.

List of Subjects in 5 CFR Parts 890 and 892

Administrative practice and procedure, Employee benefit plans, Government employees, Reporting and recordkeeping requirements, Retirement.

John Berry,

Director, U.S. Office of Personnel Management.

Accordingly, OPM is proposing to amend 5 CFR parts 890 and 892 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

1. The authority citation for part 890 is revised to read as follows:

Authority: 5 U.S.C. 8913; § 890.301 also issued under sec. 311 of Pub. L. 111–03, 123 Stat. 64; § 890.111 also issued under section 1622(b) of Pub. L. 104–106, 110 Stat. 521; § 890.112 also issued under section 1 of Pub. L. 110–279, 122 Stat. 2604; 5 U.S.C. 8913; § 890.803 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended; § 890.102 also issued under sections 11202(f), 11232(e), 11246 (b) and (c) of Pub. L. 105–33, 111 Stat. 251; and section 721 of Pub. L. 105–261, 112 Stat. 2061.

Subpart A—Administration and General Provisions

2. Add § 890.112 to subpart A to read as follows:

§ 890.112 Continuation of coverage for certain Senate Restaurants employees.

(a) A Senate Restaurants employee who was an employee of the Architect of the Capitol on July 17, 2008, who accepted employment with the private business concern to which the Senate Restaurants' food service operations were transferred as described in section 1 of Public Law 110–279, and who elected to continue his or her Federal employee retirement benefits is deemed to be an employee for purposes of this part during continuous employment with the private business concern or its successor. The individual shall be entitled to the benefits of, and be subject to all conditions under, the FEHB Program on the same basis as if the individual were an employee of the Federal Government.

(b) Cessation of employment with the private business concern or its successor for any period terminates eligibility for coverage under the FEHB Program as an employee during any subsequent employment by the private business concern.

(c) The private business concern or its successor must make arrangements for the withholding from pay of an individual described by paragraph (a) of this section of an amount equal to the premiums withheld from Federal employees' pay for FEHB coverage and, in accordance with procedures established by OPM, pay into the Employees Health Benefits Fund the amounts deducted from the individual's pay.

(d) The private business concern or its successor shall, in accordance with procedures established by OPM, pay into the Employees Health Benefits Fund amounts equal to any agency contributions required under the FEHB Program.

Subpart B—Health Benefits Plans

3. Revise § 890.201(b)(3) to read as follows:

§ 890.201 Minimum standards for health benefits plans.

* * * * *

(b) * * *

(3)(i) Have more than two options and a high deductible health plan (26 U.S.C. 223(c)(2)(A)) if the plan is described under 5 U.S.C. 8903(1) or (2); or

(ii) Have either more than three options, or more than two options and a high deductible health plan (26 U.S.C. 223(c)(2)(A)) if the plan is described under 5 U.S.C. 8903(3) or (4).

* * * * *

Subpart C—Enrollment

4. Amend § 890.301 as follows:

a. Revise paragraph (f)(1) to read as set forth below.

b. Add a new paragraph (m) to read as set forth below.

§ 890.301 Opportunities for employees who are not participants in premium conversion to enroll or change enrollment; effective dates.

* * * * *

(f) * * * (1) An open season will be held each year from November 1st through November 30th.

* * * * *

(m) *An employee or eligible family member becomes eligible for premium assistance under Medicaid or a State Children's Health Insurance Program (CHIP).* An eligible employee may enroll and an enrolled employee may change his or her enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the employee or an eligible family member of the employee becomes eligible for premium assistance under a Medicaid plan or CHIP. An employee must enroll or change his or her enrollment within 60 days after the date the employee or family member is determined to be eligible for assistance.

PART 892—FEDERAL FLEXIBLE BENEFITS PLAN: PRE–TAX PAYMENT OF HEALTH BENEFITS PREMIUMS

5. The authority citation for part 892 is revised to read as follows:

Authority: 5 U.S.C 8913; 5 U.S.C. 1103(a)(7); 26 U.S.C. 125; § 892.101 also issued under sec. 311 of Pub. L. 111–3, 123 Stat. 64.

6. In § 892.101, amend the definition of *qualifying life event* by adding a new paragraph (13) to read as follows:

§ 892.101 Definitions.

* * * * *

Qualifying life event * * *

(13) An employee or eligible family member becomes eligible for premium assistance. An eligible employee may enroll and an enrolled employee may change his or her enrollment from self only to self and family, from one plan

or option to another, or make any combination of these changes when the employee or an eligible family member of the employee becomes eligible for premium assistance under a Medicaid plan or a State Children's Health Insurance Program. An employee must enroll or change his or her enrollment within 60 days after the date the employee or family member is determined to be eligible for assistance.

[FR Doc. 2010–8957 Filed 4–16–10; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210, 215, 220, 225, and 226

RIN 0584–AE03

Geographic Preference Option for the Procurement of Unprocessed Agricultural Products in Child Nutrition Programs

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rule.

SUMMARY: The 2008 Farm Bill amended the Richard B. Russell National School Lunch Act to direct that the Secretary of Agriculture encourage institutions operating Child Nutrition Programs to purchase unprocessed locally grown and locally raised agricultural products. Effective October 1, 2008, institutions receiving funds through the Child Nutrition Programs may apply an optional geographic preference in the procurement of unprocessed locally grown or locally raised agricultural products. This provision applies to institutions in all of the Child Nutrition Programs, including the National School Lunch Program, School Breakfast Program, Fresh Fruit and Vegetable Program, Special Milk Program for Children, Child and Adult Care Food Program and Summer Food Service Program, as well as to purchases made for these programs by the Department of Defense Fresh Program. The provision also applies to State Agencies making purchases on behalf of any of the aforementioned Child Nutrition Programs. The purpose of this proposed rule is to incorporate this procurement option in the Programs' regulations and to define the term "unprocessed locally grown or locally raised agricultural products" to ensure that both the intent of Congress in providing for such a procurement option is met and that any such definition will facilitate ease of implementation for institutions participating in the Child Nutrition Programs. The proposed rule is intended to be implemented by institutions choosing to apply the geographic preference option for the procurement of locally grown and locally raised agricultural products.

DATES: Comments must be received on or before June 18, 2010 to be assured of consideration.

ADDRESSES: The Food and Nutrition Service, USDA, invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- *Federal e-Rulemaking Portal:* Go to *http://www.regulations.gov*. Preferred method; follow the online instructions for submitting comments.
- *Fax: Submit comments by facsimile transmission to:* (703) 305–2879, Attention: Melissa Rothstein.
- *Mail:* Comments should be addressed to Melissa Rothstein, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 634, Alexandria, Virginia 22302.
- *Hand Delivery or Courier:* Deliver comments to 3101 Park Center Drive, Room 634, Alexandria, Virginia 22302–1594, during normal business hours of 8:30 a.m.–5 p.m.
- All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the comments publicly available on the Internet via *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Melissa Rothstein, Chief, Policy and Program Development Branch at the above address or by telephone at (703) 305–2590.

SUPPLEMENTARY INFORMATION:

Background

Section 4302 of Public Law 110–246, the Food, Conservation, and Energy Act of 2008, amended section 9(j) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1758(j)) to require the Secretary of Agriculture to encourage institutions operating Child Nutrition Programs to purchase unprocessed locally grown and locally raised agricultural products. Pursuant to section 4407 of Public Law 110–246, beginning October 1, 2008, institutions receiving funds as participants in the Child Nutrition Programs may apply an optional geographic preference in the procurement of unprocessed locally grown or locally raised agricultural products. This provision applies to institutions operating all of the Child Nutrition Programs, including the National School Lunch Program, School Breakfast Program, Fresh Fruit and Vegetable Program, Special Milk Program, Child and Adult Care Food Program and Summer Food Service Program, as well as to purchases made for these programs by the Department of Defense Fresh Program. The provision does not apply to purchases made by the Department. However, the provision does also apply to State agencies making purchases on behalf of any of the aforementioned Child Nutrition Programs. We initially implemented the provisions through policy memoranda and explanatory question and answer communications dated January 9, 2009, July 22, 2009 and October 9, 2009.

Traditionally, a geographic preference established for a procurement provides bidders located in a specified geographic area additional points or credit calculated during the evaluation of the proposals or bids received in response to a solicitation. A geographic preference is not a procurement set-aside for bidders located in the specified geographic area, guaranteeing them a certain level or percentage of business. In addition, including a geographic preference in a procurement does not preclude a bidder from outside the specified geographic area from competing for, and possibly being awarded, the contract subject to the geographic preference. Rather, a geographic preference is a tool that gives bidders in a specified geographic area a specific, defined advantage in the procurement process.

By utilizing the statutorily established geographic preference option in Child Nutrition Programs, purchasing institutions, such as States, school food authorities, child care institutions and SFSP sponsors, may specifically identify the geographic area within which unprocessed locally raised and locally grown agricultural products will originate. As proposed in this rule, a responsive bidder would offer to provide unprocessed locally raised and locally grown agricultural products from the specifically identified geographic area. In most cases, we would expect that a bidder would be located in the identified geographic area, though it is possible for a responsive bidder to be located outside of that area. These procurements may be accomplished through informal or formal procurement procedures, as required by respective Child Nutrition Program regulations.

Local purchasing power not only supports increasing economic opportunities for local farmers but also helps schools and other institutions include wholesome food choices which will encourage children to make healthy food choices. Allowing a geographic procurement preference option serves to reinforce the fundamental and critical reconnection between producers and consumers. The effort builds on the 2008 Farm Bill, which provides for increases and flexibility for USDA programs in an effort to promote local foods.

The geographic preference option basically allows institutions operating Child Nutrition Programs to specifically define geographic areas from which they will seek to procure unprocessed local agricultural products. It is up to each institution, whether it be a school food authority, a child care institution or a Summer Food Service Program sponsor, to determine how to define the geographic area.

As provided in the Joint Explanatory Statement of the Committee of Conference in House Report 110–627, the term "unprocessed" precludes the use of geographic preference in procuring agricultural products that have significant value added components. The Conference report also noted the acceptability of *de minimus* handling and preparation "such as may be necessary to present an agricultural product to a school food authority in a useable form, such as washing vegetables, bagging greens, butchering livestock and poultry, pasteurizing milk, and putting eggs in a carton."

Proposed Action

We have determined that it is necessary to propose a rulemaking to define what would constitute "unprocessed agricultural products" for the purposes of implementing the geographic preference procurement option in the Child Nutrition Programs. In developing such a rule, we are proposing that the definition should:

(1) Comply with the language and reflect the intent of the statute;

(2) Ensure that any processing of agricultural products results in only minimal value added to such products; and

(3) Facilitate ease of use of such products for institutions.

In preparation for the development of this proposed rule, we researched a variety of definitions of "unprocessed food" used by a number of Federal agencies. Upon review, however, those definitions do not meet the needs of the Child Nutrition Programs.

We also researched the types of handling and processing techniques that are available to bring agricultural products to the marketplace. There are a variety of methods that may be used to process agricultural products for consumption. In addition, we would note that at least one method—pasteurization—is already a regulatory requirement for all milk served in Child Nutrition Programs. While the Conference Report discusses *de minimus* processing of such products, the geographic preference option allowed by statute prohibits the use of processing methods that add significant value to the products. This is particularly important since the geographic preference provision is a noteworthy exception to the standard procurement provisions of Child Nutrition Programs and other programs government-wide.

Based upon our research, as well as keeping in mind the intent of Congress as expressed in the Conference Report, we are proposing that the definition of "unprocessed food" specify a prohibition against any processing method that alters the inherent character of the agricultural product. To that end, we have included in the proposed definition a list of acceptable food handling and preservation techniques for purposes of applying the geographic preference procurement option. Such techniques would include: General heat transfer methods such as cooling, refrigerating and freezing; size adjustment through size reduction (peeling, slicing, dicing, cutting and grinding); drying/dehydration; vacuum packing and bagging; pasteurization for milk; cold storage; the application of high water pressure ("cold pasteurization"); butchering of livestock and poultry and the cleaning of fish. We believe that these handling and preservation techniques comply with the intent of the statute and do not alter the inherent character of agricultural products subjected to them.

The reduction of the size of larger products would not be considered as altering the inherent character of the agricultural product, nor would such size reduction add significant value to the product. For example, cutting full size carrots into smaller, student-friendly carrot sticks would not alter the inherent character of the agricultural product but would enhance its usable form. However, combining or forming any agricultural product would not meet the definition of unprocessed agricultural products as proposed. For example, while ground and frozen meat or poultry would not be considered as having had its inherent character changed, forming such a ground frozen product into a ready-to-prepare meat patty would be considered as changing the inherent character of the product while adding significant value to that product. Under the proposed definition, the geographic preference procurement option would not apply to the procurement of such products.

This proposed rule would prohibit the application of the geographic preference procurement option for products subjected to processing methods not included in the definition of "unprocessed agricultural products."

The geographic preference procurement option could only be used when purchasing locally grown and locally raised agricultural products as defined in this rule. However, once such a purchase is made, the institution would be free to have the agricultural product further processed under a separate processing contract. An institution would use regular procurement procedures in acquiring processing services to have such products processed in any way that they would like. In addition, it is important to note that, due to the geographic diversity in each state, the institution responsible for the procurement of the locally grown and locally raised product has the discretion to define the local area for which any geographic preference (e.g., State, county, region, etc.) will be applied. However, institutions should keep in mind that local preference should not be defined in a way that excludes bidders from outside the designated geographic area or otherwise unnecessarily restricts competition.

Accordingly, this rule proposes to add new paragraphs to sections 210.21, 215.14a, 220.16, 225.17 and 226.22 of Title 7, CFR, to include the geographic preference procurement option and define the term "unprocessed locally grown or locally raised agricultural products".

Applicability to the Fresh Fruit and Vegetable Program

The geographic preference procurement option is applicable to purchases made in the Fresh Fruit and Vegetable Program, 42 U.S.C. 1769a (FFVP). However, this provision shall only be applied within the context of the FFVP's requirement that produce utilized in the program be fresh. The definition of "unprocessed locally grown or locally raised agricultural products" does not change the basic statutory requirement that only *fresh* produce may be purchased using funds for the Fresh Fruit and Vegetable Program. Development of regulations

pertaining to the requirements for the Fresh Fruit and Vegetable Program are currently in process and the provisions relating to the geographic preference procurement option will be included in that proposed rule, as appropriate.

Executive Order 12866

This rule has been determined to be not significant and was not reviewed by the Office Management and Budget in conformance with Executive Order 12866.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612). It has been certified that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under Section 202 of the UMRA, the Department generally must prepare a written statement, including a cost/benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule. This rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) that impose costs on State, local, or tribal governments or to the private sector of $100 million or more in any one year. This rule is, therefore, not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The National School Lunch Program and the School Breakfast Program are listed in the Catalog of Federal Domestic Assistance under No. 10.555 and 10.553, respectively. The Special Milk Program is listed under No. 10.556. The Child and Adult Care Food Program is listed under No. 10.558 and the Summer Food Service Program for Children is listed under No. 10.559. For the reasons set forth in the final rule in 7 CFR Part 3015, Subpart V and related Notice (48 FR 29115, June 24, 1983), these programs are included in the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Executive Order 13132

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132. The Food and Nutrition Service (FNS) has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implications. This rule does not impose substantial or direct compliance costs on State and local governments. Therefore, under Section 6(b) of the Executive Order, a federalism summary impact statement is not required.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full implementation. This rule is not intended to have retroactive effect unless specified in the **DATES** section of the final rule. Prior to any judicial challenge to the provisions of this rule or the application of its provisions, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed this rule in accordance with Departmental Regulations 4300–4, "Civil Rights Impact Analysis", and 1512–1, "Regulatory Decision Making Requirements." After a careful review of the rule's intent and provisions, FNS has determined that this rule is not intended to limit or reduce in any way the ability of protected classes of individuals to receive benefits on the basis of their race, color, national origin, sex, age or disability nor is it intended to have a differential impact on minority owned or operated business establishments, and woman-owned or operated business establishments that participate in the Child Nutrition Programs. This rule simply allows institutions that participate in the Child Nutrition Programs the option to apply a geographic preference should such institutions wish to procure unprocessed locally grown or locally raised agricultural products.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR 1320) requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This rule does not contain information collection requirements subject to approval by OMB under the Paperwork Reduction Act of 1995.

E-Government Act Compliance

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

List of Subjects

7 CFR Part 210

Grant programs–education; Grant programs–health; Infants and children; Nutrition; Penalties; Reporting and recordkeeping requirements; School breakfast and lunch programs; Surplus agricultural commodities.

7 CFR Part 215

Food assistance programs; Grant programs–education; Grant programs–health; Infants and children; Milk; Reporting and recordkeeping requirements.

7 CFR Part 220

Grant programs–education; Grant programs–health; Infants and children; Nutrition; Reporting and recordkeeping requirements; School breakfast and lunch programs.

7 CFR Part 225

Food assistance programs; Grant programs–health; Infants and children; Labeling; Reporting and recordkeeping requirements.

7 CFR Part 226

Accounting; Aged; Day care; Food assistance programs; Grant programs; Grant programs–health; Indians; Individuals with disabilities; Infants and children; Intergovernmental relations; Loan programs; Reporting and recordkeeping requirements; Surplus agricultural commodities.

Accordingly, 7 CFR Parts 210, 215, 220, 225, and 226 are proposed to be amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

1. The authority citation for 7 CFR Part 210 continues to read as follows:

Authority: 42 U.S.C. 1751–1760, 1779.

2. In § 210.21, paragraph (g) is added to read as follows:

Subpart E—State Agency and School Food Authority Responsibilities

§ 210.21 Procurement.

* * * * *

(g) *Geographic preference.* (1) A school food authority participating in the Program, as well as State agencies making purchases on behalf of such school food authorities, may apply a geographic preference when procuring unprocessed locally grown or locally raised agricultural products. When utilizing the geographic preference to procure such products, the school food authority making the purchase or the State agency making purchases on behalf of such school food authorities have the discretion to determine the local area to which the geographic preference option will be applied;

(2) For the purpose of applying the optional geographic procurement preference in paragraph (g)(1) of this section, "unprocessed locally grown or locally raised agricultural products" means only those agricultural products that retain their inherent character. The effects of the following food handling and preservation techniques shall not be considered as changing an agricultural product into a product of a different kind or character: cooling; refrigerating; freezing; size adjustment made by peeling, slicing, dicing, cutting, chopping, shucking, and grinding; drying/dehydration; washing; applying high water pressure or "cold pasteurization"; packaging (such as placing eggs in cartons), vacuum packing and bagging (such as placing vegetables in bags); butchering livestock and poultry; cleaning fish; and the pasteurization of milk.

PART 215—SPECIAL MILK PROGRAM FOR CHILDREN

3. The authority citation for 7 CFR Part 215 continues to read as follows:

Authority: 42 U.S.C. 1772 and 1779.

4. In § 215.14a, paragraph (e) is added to read as follows:

§ 215.14a Procurement standards.

* * * * *

(e) *Geographic preference.* A school food authority participating in the Program may apply a geographic preference when procuring milk. When utilizing the geographic preference to procure milk, the school food authority making the purchase has the discretion to determine the local area to which the geographic preference option will be applied.

* * * * *

PART 220—SCHOOL BREAKFAST PROGRAM

5. The authority citation for 7 CFR Part 220 continues to read as follows:

Authority: 42 U.S.C. 1773, 1779, unless otherwise noted.

6. In § 220.16, paragraph (f) is added to read as follows:

§ 220.16 Procurement.

* * * * *

(f) *Geographic preference.* (1) School food authorities participating in the Program, as well as State agencies making purchases on behalf of such school food authorities, may apply a geographic preference when procuring unprocessed locally grown or locally raised agricultural products. When utilizing the geographic preference to procure such products, the school food authority making the purchase or the State agency making purchases on behalf of such school food authorities have the discretion to determine the local area to which the geographic preference option will be applied;

(2) For the purpose of applying the optional geographic preference in paragraph (f)(1) of this section, "unprocessed locally grown or locally raised agricultural products" means only those agricultural products that retain their inherent character. The effects of the following food handling and preservation techniques shall not be considered as changing an agricultural product into a product of a different kind or character: Cooling; refrigerating; freezing; size adjustment made by peeling, slicing, dicing, cutting, chopping, shucking, and grinding; drying/dehydration; washing; applying high water pressure or "cold pasteurization"; packaging (such as placing eggs in cartons), vacuum packing and bagging (such as placing vegetables in bags); butchering livestock and poultry; cleaning fish; and the pasteurization of milk.

* * * * *

PART 225—SUMMER FOOD SERVICE PROGRAM

7. The authority citation for 7 CFR Part 225 continues to read as follows:

Authority: Secs. 9, 13 and 14, Richard B. Russell National School Lunch Act, as amended, (42 U.S.C. 1758, 1761 and 1762a).

8. In § 225.17, paragraph (e) is added to read as follows:

§ 225.17 Procurement standards.

* * * * *

(e) *Geographic preference.* (1) Sponsors participating in the Program may apply a geographic preference when procuring unprocessed locally grown or locally raised agricultural products. When utilizing the geographic preference to procure such products, the sponsor making the purchase has the discretion to determine the local area to which the geographic preference option will be applied;

(2) For the purpose of applying the optional geographic preference in paragraph (e)(1) of this section, "unprocessed locally grown or locally raised agricultural products" means only those agricultural products that retain their inherent character. The effects of the following food handling and preservation techniques shall not be considered as changing an agricultural product into a product of a different kind or character: Cooling; refrigerating; freezing; size adjustment made by peeling, slicing, dicing, cutting, chopping, shucking, and grinding; drying/dehydration; washing; applying high water pressure or "cold pasteurization"; packaging (such as placing eggs in cartons), vacuum packing and bagging (such as placing vegetables in bags); butchering livestock and poultry; cleaning fish; and the pasteurization of milk.

PART 226—CHILD AND ADULT CARE FOOD PROGRAM

9. The authority citation for 7 CFR Part 226 continues to read as follows:

Authority: Secs. 9, 11, 14, 16, 17, Richard B. Russell National School Lunch Act, as amended (42 U.S.C. 1758, 1759a, 1762a, 1765 and 1766).

10. In § 226.22, paragraph (n) is added to read as follows:

§ 226.22 Procurement standards.

* * * * *

(n) *Geographic preference.* (1) Institutions participating in the Program may apply a geographic preference when procuring unprocessed locally grown or locally raised agricultural products. When utilizing the geographic preference to procure such products, the

institution making the purchase has the discretion to determine the local area to which the geographic preference option will be applied;

(2) For the purpose of applying the optional geographic preference in paragraph (n)(1) of this section, "unprocessed locally grown or locally raised agricultural products" means only those agricultural products that retain their inherent character. The effects of the following food handling and preservation techniques shall not be considered as changing an agricultural product into a product of a different kind or character: Cooling; refrigerating; freezing; size adjustment made by peeling, slicing, dicing, cutting, chopping, shucking, and grinding; drying/dehydration; washing; applying high water pressure or "cold pasteurization"; packaging (such as placing eggs in cartons), vacuum packing and bagging (such as placing vegetables in bags); butchering livestock and poultry; cleaning fish; and the pasteurization of milk.

Dated: April 8, 2010.

Julia M. Paradis,

Administrator, Food and Nutrition Service.

[FR Doc. 2010–8850 Filed 4–16–10; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2010–0285; Airspace Docket No. 10–ASO–23]

Amendment of Class E Airspace; Smithfield, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E Airspace at Smithfield, NC, to accommodate the additional airspace needed for the Standard Instrument Approach Procedures (SIAPs) developed for Johnston County Airport. This action enhances the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport.

DATES: 0901 UTC. Comments must be received on or before June 3, 2010.

ADDRESSES: Send comments on this rule to: U. S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001; *Telephone:* 1–800–647–5527; *Fax:* 202–493–2251. You must identify the Docket Number FAA–2010–0285; Airspace Docket No. 10–ASO–23, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Melinda Giddens, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5610.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2010–0285; Airspace Docket No. 10–ASO–23) and be submitted in triplicate to the Docket Management System (*see* **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA–2010–0285; Airspace Docket No. 10–ASO–23." The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, room 210, 1701 Columbia Avenue, College Park, Georgia 30337.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory circular No. 11–2A, Notice of Proposed Rulemaking distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to establish Class E airspace at Smithfield, NC to provide controlled airspace required to support the SIAPs for Johnston County Airport. The existing Class E airspace extending upward from 700 feet above the surface would be modified for the safety and management of IFR operations.

Class E airspace designations are published in Paragraph 6005 of FAA order 7400.9T, signed August 27, 2009, and effective September 15, 2009, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (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) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in

Title 49 of the United States Code. 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. This proposed rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would amend Class E airspace at Johnston County Airport, Smithfield, NC.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND CLASS E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, effective September 15, 2009, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO NC E5 Smithfield, NC [Amended]

Johnston County Airport, NC
(Lat. 35°32′27″ N., long. 78°23′25″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Johnston County Airport and within 2 miles each side of the 023° bearing from the airport extending from the 6.5-mile radius to 10.2 miles northeast of the Johnston County Airport.

Issued in College Park, Georgia, on April 9, 2010.

Signed By:

Myron A. Jenkins,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2010–8855 Filed 4–16–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2009–1220; Airspace Docket No. 09–ANM–30]

Proposed Amendment of Class E Airspace; Bozeman, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace at Gallatin Field Airport, Bozeman, MT, to accommodate aircraft using a new VHF Omni-Directional Radio Range (VOR) Standard Instrument Approach Procedure (SIAP) at Gallatin Field Airport. This action would enhance the safety and management of aircraft operations at the airport.

DATES: Comments must be received on or before June 3, 2010.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2009–1220; Airspace Docket No. 09–ANM–30, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA 2009–1220 and Airspace Docket No. 09–ANM–30) and be submitted in triplicate to the Docket Management System (*see* **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov*.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA–2009–1220 and Airspace Docket No. 09–ANM–30." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (*see* the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class E airspace at Gallatin Field Airport, Bozeman, MT. Additional controlled airspace designated as an extension to a Class D surface area, and airspace extending upward from 700 feet above the surface, is necessary to accommodate aircraft using the new VOR SIAP's at Gallatin Field Airport, Bozeman, MT. This action would enhance the safety and management of instrument flight rules operations at the airport.

Class E airspace designations are published in paragraph 6004 and 6005, respectively, of FAA Order 7400.9T, signed August 27, 2009, and effective September 15, 2009, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify controlled airspace at Gallatin Field Airport, Bozeman, MT.

List of Subjects in 14 CFR Part 71

Airspace, incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the FAA Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and effective September 15, 2009 is amended as follows:

Paragraph 6004—Class E airspace are as designated as an Extension to a Class D surface area.

* * * * *

ANM MT E4 Bozeman, MT [Modified]

Bozeman, Gallatin Field Airport, MT
(Lat. 45°46′37″ N., long. 111°09′07″ W.)

That airspace extending upward from the surface within 3 miles each side of the 316° bearing of Gallatin Field Airport, extending from the 4.4-mile radius of the airport to 14 miles northwest of Gallatin Field Airport; and that airspace 2.4 miles each side of the 212° bearing of the Gallatin Field Airport, extending from the 4.4-mile radius of the airport to 7 miles northwest of Gallatin Field Airport.

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM MT E5 Bozeman, MT [Modified]

Bozeman, Gallatin Field Airport, MT
(Lat. 45°46′37″ N., long. 111°09′07″ W.)

That airspace extending upward from 700 feet above the surface within a 13.5-mile radius of Gallatin Field Airport, and within 4.8 miles northeast and 13 miles southwest of the 316° bearing of the airport extending from the 13.5-mile radius to 24.4 miles northwest of Gallatin Field Airport.

Issued in Seattle, Washington, on April 7, 2010.

Robert E. Henry,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2010–8854 Filed 4–16–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2009–1135; Airspace Docket No. 09–ANM–20]

Proposed Amendment of Class E Airspace; Kelso, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace at Southwest Washington Regional Airport, Kelso, WA, to accommodate aircraft using the new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAP's) at Southwest Washington Regional Airport. The FAA is proposing this action to enhance the safety and management of aircraft operations at the airport. This action will also change the airport name from Kelso-Longview Airport.

DATES: Comments must be received on or before June 3, 2010.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590; Telephone (202) 366–9826. You must identify FAA Docket No. FAA–2009–1135; Airspace Docket No. 09–ANM–20, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; Telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA

2009–1135 and Airspace Docket No. 09–ANM–20) and be submitted in triplicate to the Docket Management System (*see* **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov*.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA–2009–1135 and Airspace Docket No. 09–ANM–20." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (*see* the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class E airspace extending upward from 700' above the surface at Southwest Washington Regional Airport, Kelso, WA. Additional controlled airspace is necessary to accommodate aircraft using the new RNAV (GPS) SIAP's at Southwest Washington Regional Airport. This action would enhance the safety and management of aircraft operations at the airport. This action also would change the airport name from Kelso-Longview Airport, to Southwest Washington Regional Airport.

Class E airspace designations are published in paragraph 6005, of FAA Order 7400.9T, signed August 27, 2009, and effective September 15, 2009, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would add additional controlled airspace at Southwest Washington Regional Airport, Kelso, WA.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the FAA Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and effective September 15, 2009 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM WA, E5 Kelso, WA [Modified]

Southwest Washington Regional Airport, WA
(Lat. 46°07′05″ N., long. 122°53′54″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Southwest Washington Regional Airport, and 2.4 miles each side of the 290° bearing of the airport extending 9.1 miles west, and 4.3 miles each side of the 337° bearing of the airport extending 22.2 miles northwest, and 5.8 miles west and 3 miles east of the 012° bearing of the airport extending 18.2 miles north of the airport.

Issued in Seattle, Washington, on April 7, 2010.

Robert E. Henry,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2010–8853 Filed 4–16–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2009–1050; Airspace Docket No. 09–ASW–40]

RIN 2120–AA66

Proposed Amendment to and Establishment of Restricted Areas and Other Special Use Airspace; Razorback Range Airspace Complex, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); correction.

SUMMARY: This action corrects a NPRM published in the **Federal Register** March 30, 2010. In that NPRM, the airspace docket number was incorrectly published as "09–ASW–3" instead of "09–ASW–40." This action corrects that error.

DATES: Effective date 0901 UTC, April 19, 2010. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace and Rules Group, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; *telephone:* (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

On March 30, 2010, a NPRM for Airspace Docket No. 09–ASW–3, FAA Docket No. FAA–2009–1050, was published in the **Federal Register** (75 FR 15632) to amend and establish restricted areas and other special use airspace in the Razorback Range Airspace Complex, AR. The airspace docket number in that NPRM was incorrect and should have read "09–ASW–40" instead of "09–ASW–3." This action corrects that error.

Correction to Proposed Rule

Accordingly, pursuant to the authority delegated to me, in proposed rule FAA Docket No. FAA–2009–1050, on March 30, 2010 (75 FR 15632), make the following correction:

§ 71.1 [Amended]

On page 15632, columns 2, and 3, and on page 15633, column 1, correct the airspace docket number to read as follows: Airspace Docket No. 09–ASW–40.

Issued in Washington, DC, on April 8, 2010.

Edith V. Parish,

Manager, Airspace and Rules Group.

[FR Doc. 2010–8829 Filed 4–16–10; 8:45 am]

BILLING CODE 4910–13–P

Notices

Federal Register
Vol. 75, No. 74
Monday, April 19, 2010

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

Rural Housing Service

Notice of Intent To Hold Public Forums To Solicit Feedback From the Public Regarding the Section 523 Mutual Self-Help Housing Program

AGENCY: Rural Housing Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Housing Service, USDA published a document in the Federal Register of February 2, 2010, concerning upcoming public forums and request for comments regarding the Section 523 Mutual Self-Help Housing Program. There has been a change in the date to receive written comments, a change in one of the forum dates and a change in contact information.

FOR FURTHER INFORMATION CONTACT: Carolyn L. Bell, Chief, Special Program and New Initiatives Branch, Single Family Housing Direct Loan Division, Rural Housing Service, USDA at 1400 Independence Avenue, SW., Stop 0783, Washington, DC 20250–0783, telephone (202) 720–1532, fax: (202) 720–2232, e-mail *carolyn.bell@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION: The date for all written questions and comments to be received has been changed to July 15, 2010, and the date for Washington, DC has been changed to June 30, 2010.

Dated: April 9, 2010.

Kathy Mcentee,

Acting Administrator, Rural Housing Service.

[FR Doc. 2010–8907 Filed 4–16–10; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF COMMERCE

Office of the Secretary

Notice of an Opportunity To Serve on the Board of Directors of the Corporation for Travel Promotion

AGENCY: Office of the Secretary, U.S. Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce is inviting expressions of interest to serve on the initial Board of Directors of the Corporation for Travel Promotion (Board) from leaders with knowledge of international travel promotion and marketing and who have expertise and experience in specific sectors of the travel and tourism industry. The purpose of the initial Board is to, among other things, serve as incorporators and establish the Corporation for Travel Promotion.

DATES: All information must be received by the Office of the Secretary at the email or postal address below by close of business (EDT) on May 10, 2010.

ADDRESSES: Please submit relevant information via e-mail to *TPABoard@doc.gov* or by mail to John Connor, Office of the Secretary, U.S. Department of Commerce, Room 5835, 1401 Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

The Travel Promotion Act of 2009 (TPA) was passed on February 25, 2010 and signed into law on March 4, 2010. The TPA establishes the Corporation for Travel Promotion (Corporation), a non-profit corporation that will communicate United States entry policies and otherwise promote leisure, business, and scholarly travel to the United States.

The TPA states that the Corporation shall develop and execute a plan to (A) provide useful information to those interested in traveling to the United States; (B) identify and address perceptions regarding U.S. entry policies; (C) maximize economic and diplomatic benefits of travel to the United States through the use of various promotional tools; and (D) ensure that international travel benefits all States and the District of Columbia, and identify opportunities to promote tourism to rural and urban areas equally, including areas not traditionally visited by international travelers.

The Corporation will be governed by a board of directors of eleven members with knowledge of international travel promotion and marketing and with appropriate expertise and experience in specific sectors of the travel and tourism industry. These members will broadly represent various regions of the United States.

Selection Criteria

The TPA directs the Secretary of Commerce (after consultation with the Secretary of Homeland Security and the Secretary of State) to appoint the board of directors for the Corporation for Travel Promotion. Thus, in accordance with the TPA, the Department of Commerce will be selecting individuals with the appropriate expertise and experience from specific sectors of the travel and tourism industry to serve on the Board as follows:

(A) 1 shall have appropriate expertise and experience in the hotel accommodations sector;

(B) 1 shall have appropriate expertise and experience in the restaurant sector;

(C) 1 shall have appropriate expertise and experience in the small business or retail sector or in associations representing that sector;

(D) 1 shall have appropriate expertise and experience in the travel distribution services sector;

(E) 1 shall have appropriate expertise and experience in the attractions or recreations sector;

(F) 1 shall have appropriate expertise and experience as officials of a city convention and visitors' bureau;

(G) 2 shall have appropriate expertise and experience as officials of a State tourism office;

(H) 1 shall have appropriate expertise and experience in the passenger air sector;

(I) 1 shall have appropriate expertise and experience in immigration law and policy, including visa requirements and United States entry procedures; and

(J) 1 shall have appropriate expertise in the intercity passenger railroad business.

To be eligible for Board membership, one must have international travel and tourism marketing experience and must also be a U.S. citizen. In addition, individuals cannot be federally registered lobbyists or registered as a

foreign agent under the Foreign Agents Registration Act of 1938, as amended.

Those selected for the initial Board must be able to meet the time and effort commitments of the Board to establish the new Corporation.

Priority may be given to individuals with experience as a Chief Executive Officer or President (or comparable level of responsibility) of an organization or entity in the travel and tourism sector in the United States.

Board members will serve at the discretion of the Secretary of Commerce (who may remove any member of the Board for good cause).

The term of office of each member of the Board will be 3 years, except that, of the members first appointed: (A) 3 shall be appointed for terms of 1 year; (B) 4 shall be appointed for terms of 2 years; and (C) 4 shall be appointed for terms of 3 years. Board members can serve a maximum of two consecutive full three-year terms.

Board members are not considered Federal government employees by virtue of their service as a member of the Board and will receive no compensation from the Federal government for their participation in Board activities. Members participating in Board meetings and events will be paid actual travel expenses and per diem when away from their usual places of residence.

To be considered for membership, please provide the following:

1. Name, title, and personal resume of the individual requesting consideration; and

2. A brief statement of why the person should be considered for membership on the Board. This statement should also address the individual's relevant international travel and tourism marketing experience and indicate clearly the sector or sectors enumerated above in which the individual has the requisite expertise and experience. Individuals who have the requisite expertise and experience in more than one sector can be appointed from only one of those sectors.

Appointments of members to the Board will be made by the Secretary of Commerce.

Dated: April 13, 2010.

John Connor,

Director, Office of the Secretary.

[FR Doc. 2010–8856 Filed 4–16–10; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No. 100407180–0181–01]

Technology Innovation Program (TIP) Notice of Availability of Funds and Announcement of Public Meetings (Proposers' Conferences)

AGENCY: National Institute of Standards and Technology (NIST), Department of Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology's (NIST) Technology Innovation Program (TIP) announces that it will hold a single fiscal year 2010 competition and is soliciting high-risk, high-reward research and development (R&D) proposals for financial assistance. TIP also announces that it will hold three public meetings (Proposers' Conferences) for all interested parties. TIP is soliciting proposals under this fiscal year 2010 competition in the area of critical national need entitled "Manufacturing" as described in the Program Description section below.

DATES: The due date for submission of proposals is 11:59 p.m. Eastern Time, Thursday, July 15, 2010. This deadline applies to any mode of proposal submission, including paper and electronic. Do not wait until the last minute to submit a proposal. TIP will not make any allowances for late submissions, including incomplete Grants.gov registration or delays by guaranteed overnight couriers. To avoid any potential processing backlogs due to last minute registrations, proposers are strongly encouraged to start their Grants.gov registration process at least four weeks prior to the proposal submission due date. Review, selection, and award processing is expected to be completed by the end of November 2010.

ADDRESSES: Proposals must be submitted to TIP as follows:

Paper submission: Send to National Institute of Standards and Technology, Technology Innovation Program, 100 Bureau Drive, Stop 4750, Gaithersburg, MD 20899–4750. Please note that the NIST site is closed to the general public, and applicant personnel and couriers will not be permitted onto the NIST site in order to deliver proposals. Also note that the NIST Visitors Center is not permitted to accept proposals on behalf of the Technology Innovation Program. Paper submissions will be accepted from the U.S. Mail or similar commercial carrier that routinely delivers mail to NIST.

Electronic submission: http://www.grants.gov.

FOR FURTHER INFORMATION CONTACT: Thomas Wiggins at 301–975–5416 or by e-mail at *thomas.wiggins@nist.gov.*

SUPPLEMENTARY INFORMATION:

Additional Information: The full Federal Funding Opportunity (FFO) announcement for this request for proposals contains detailed information and requirements for the program. Proposers are strongly encouraged to read the FFO in developing proposals. The full FFO announcement text is available at *http://www.grants.gov* and on the TIP Web site at *http://www.nist.gov/tip/helpful-resources.cfm.* In addition, proposers are directed to review the April 2010 Technology Innovation Program Proposal Preparation Kit available at *http://www.nist.gov/tip/helpful-resources.cfm.* The TIP Proposal Preparation Kit must be used to prepare a TIP proposal. The TIP implementing regulations are published at 15 CFR Part 296, and included in the TIP Proposal Preparation Kit as Appendix B.

Public Meetings (Proposers' Conferences): TIP will hold three public meetings (Proposers' Conferences) to provide general information regarding TIP, to offer guidance on preparing proposals, and to answer questions. Proprietary technical discussions about specific project ideas with NIST staff are not permitted at these conferences or at any time before submitting the proposal to TIP. Therefore, proposers should not expect to have proprietary issues addressed at the Proposers' Conferences. Also, NIST/TIP staff will not critique or provide feedback on project ideas while they are being developed by a proposer. However, NIST/TIP staff will answer questions about the TIP eligibility and cost-sharing requirements, evaluation and award criteria, selection process, and the general characteristics of a competitive TIP proposal at the Proposers' Conferences and by phone and e-mail. Attendance at the TIP Proposers' Conferences is not required.

The TIP Proposers' Conferences will be held on the following dates, times, and at the following locations:

(1) April 28, 2010, 9 a.m.–2 p.m. Eastern Time: NIST Red Auditorium, 100 Bureau Drive, Gaithersburg, MD. Pre-registration is required by 5 p.m. Eastern Time on April 23, 2010, for the Proposers' Conference being held at NIST Gaithersburg, MD. Due to increased security at NIST, NO on-site registrations will be accepted and all attendees MUST be pre-registered.

Photo identification must be presented at the NIST main gate to be admitted to the April 28, 2010 conference. Attendees must wear their conference badge at all times while on the NIST campus. Electronic Registration at: *http://www.nist.gov/public_affairs/confpage/100428.htm.*

No registration fee will be charged for attending the Proposers' Conferences. Presentation materials from the Gaithersburg, MD Proposers' Conference will be made available on the TIP Web site.

The Gaithersburg, MD Proposers' Conference will webcast details at the TIP Web site: *http://www.nist.gov/tip.*

(2) May 4, 2010, 1 p.m.–5 p.m. Pacific Time, Embassy Suites Hotel Los Angeles International Airport—South, 1440 Imperial Avenue, El Segundo, CA 90245.

(3) May 6, 2010, 9:00 a.m.–1 p.m. Eastern Time, Detroit Marriott Renaissance Center, Renaissance Drive N, Detroit, MI 48243.

No Pre-registration is required for the Proposers' Conferences in Los Angeles, CA or Detroit, MI.

Statutory Authority: Section 3012 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act, Pub. L. 110–69 (August 9, 2007), codified at 15 U.S.C. 278n.

CFDA: 11.616, Technology Innovation Program.

Program Description: TIP is soliciting proposals under this fiscal year 2010 competition in the area of critical national need entitled "Manufacturing" as described below.

Area of Critical National Need: Manufacturing

The goal of the research outcome/impacts from this competition is to provide manufacturers and end users improved access to adequate quantities of materials based on new advances at competitive costs that allow evaluation and utilization of these materials in innovative ways, and new manufacturing processes that can transform the way products are made. TIP's funding strategy for this competition will emphasize three important elements: (1) Process scale-up, integration and design for materials advances; (2) Predictive modeling for materials advances and materials processing; and (3) Critical process advances related to the manufacturability of materials and manufacturing of both new and existing products. These three elements of the societal challenge of accelerating the use of materials advances and advances in critical processes will be addressed as outlined in the white paper *Manufacturing and Biomanufacturing: Materials Advances and Critical Processes* (*http://www.nist.gov/tip/cur_comp/index.cfm*).

Materials performance is often a critical consideration and controlling factor in the innovation process. High strength alloys are used to build stronger, lighter and safer vehicles; superalloys are used to make higher efficiency gas turbines; composites make larger, more efficient wind turbine blades and provide improved performance in aerospace applications; and nanomaterials are finding their way into better performing batteries, energy storage devices, electronic inks, high voltage transmission lines, and health care related applications (*e.g.,* imaging and therapeutics). Ceramics have new uses in improving electronic and photonic devices, and glasses have many next-generation applications such as wireless communication, displays, optical telecommunication, integrated circuits, and ion exchange membranes for fuel cells. Overcoming scale-up issues of moving novel materials advances from the laboratory into manufacturing through "faster, better, cheaper" methods is just one way to help manufacturers be more successful and competitive. Critical processes are generally manufacturing processes that have the greatest impact on one or more of the following characteristics: product quality, product yields from raw materials, scrap rates, efficiency of raw material consumption, and/or other measures of efficiency. Many critical manufacturing processes are not flexible enough to easily incorporate novel materials advances into new products and many critical processes limit the nation's capacity to supply existing strategically important products. Finding technical solutions to these challenges in manufacturing can give the comparative advantages necessary for retaining manufacturing in the United States. Outlined in this announcement are three key areas related to the manufacturability of materials advances and enhanced processing capabilities and descriptions of the supporting technical challenges that need to be addressed. If successful, the manufacturing solutions envisioned will have the potential to:

> Create significant improvements in new and existing products and in their manufacture by accelerating the utilization of materials advances and overcoming critical manufacturing process bottlenecks to improve the competitiveness of U.S. manufacturers in the global marketplace.

"*Materials advances*" are defined for purposes of this funding opportunity as:

> Materials that have been developed to the point that unique functionalities have been identified and these materials now need to be made available in quantities large enough for innovators and manufacturers to test and validate in order to develop new products.

The unique functionality that these materials represent will require new levels of understanding in the sciences of materials processing and process control. Nanomaterials, for example, will require manipulation and measurement at the atomic level. In alloys, the measurements and control would be at the microscale (and eventually at the nanoscale) with an emphasis on anisotropic features of the micro (nano) structure. With composites, ceramics, and glasses, measurements and control would be at the mesoscale and would take advantage of the anisotropic layering of the process. Control of one material or phase within another will also be an important consideration.

A "*critical process*" is defined for purposes of this funding opportunity as:

> A process that has a significant impact on capacity, output, quality, variability, efficiencies, performance, flexibility, etc., as well as a manufacturer's competitiveness and success.

Process improvements made through high-risk, high-reward research and development, rather than simple engineering improvements or redesign, could lead to significant and quantifiable improvements in process output measures. As an example from last year's news headlines, consider the vaccine production response to the H1N1 flu outbreak. Experts were able to decode the virus to prepare a vaccine in record time, but encountered problems supplying the large volumes of vaccine needed in a timely fashion. Vaccines are grown in chicken eggs in a process that dates back to World War II. Each egg is in effect its own factory with product variability and purity issues. Development of new processes for production of recombinant vaccines as well as processes for real time monitoring and analysis could address these problems and would help to not only respond rapidly to new virus outbreaks, but could also reduce the cost of clinical trials through better scale-up methodologies. Addressing these challenges and needs could also impact other industries such as chemicals, biofuels, *etc.*

Element 1—Process Scale-Up, Integration, and Design for Materials Advances

New materials typically are developed in a laboratory setting, and then samples are given to end-users for alpha and beta testing. During this testing phase, it can take considerable time and experimentation to understand how the materials can be incorporated into a new product in a way that maintains and utilizes their unique functionality. Scaling-up from laboratory quantities to larger volumes, validating properties, and then incorporating the materials into product manufacturing lines is often non-linear and does not follow straightforward scaling laws, due to the unique functionality that has been obtained from the materials advances.

Element 2—Predictive Modeling Tools for Materials Advances and Materials Processing

Predictive modeling capabilities are key to developing new processes, scaling-up these processes, and understanding how to utilize the unique functionality of materials advances. Modeling capabilities are needed principally to:

a. Analyze and understand why newly discovered materials do what they do and then extrapolate their behavior to new uses; and

b. Incorporate this knowledge more efficiently into process design tools so new products can be made while maintaining the unique functionality of the materials as predicted.

Element 3—Critical Process Advances

As the availability of new materials increases and the modeling of their behavior becomes more refined, there is a complementary need to improve processing or manufacturing methods. High-risk, high-reward approaches are needed to exploit the properties of the materials advances into new and more advanced products as well as support the processing of existing materials in new and different ways, resolving key bottlenecks or critical problems such as energy consumption, processing time, scrap rates, quality, and throughput. Current methods of manufacturing often are not rapidly adaptable to making new or different products, and are often not optimized towards making existing products faster, more cheaply, and more sustainably. Improving processes used in the manufacture of new and existing products is an imperative for the continued global competitiveness of U.S. manufacturers. Agile, flexible, and increasingly interoperable systems are necessary enhancements to base manufacturing technologies in order to meet new productivity challenges.

Significant biomanufacturing process improvements are needed to enhance safety, quality, and consistency of biopharmaceuticals while reducing the manufacturing cost. For example, current sensing technologies typically require manual sampling, are not rapid or robust to cleaning agents or processes, and are not sufficiently reliable for imbedding in the manufacturing environment as automated technology. Critical process advances are needed, enabling rapid on-line sensing and analytical capabilities. New tools are needed for bioprocess optimization, control and improvement to enable a cost-effective batch or continuous manufacturing process. Processes that involve integrated sensing and detection capabilities for measuring multiple parameters will be useful. Moreover, purification and separation process advances involving novel membranes and affinity reagents are needed for cost-effective downstream processing in biopharmaceutical manufacturing processes.

The first two proposed elements for *Manufacturing and Biomanufacturing: Materials Advances and Critical Processes* require research in new technologies. The table below can be used to illustrate possible relationships between key challenges. TIP would expect solutions to the first two elements to map into one or more cells in Table 1 below. It is possible that the areas below could also impact or involve health care applications and/or biomanufacturing approaches.

TABLE 1

Technological needs	Nanomaterials	Superalloys, alloys & smart materials	Composites	Ceramics	Glasses
Processing of Materials:					
Scale-up from Laboratory Quantities/Controls.					
Incorporate into New Uses/Maintain Functionality.					
Predictive Modeling:					
Rules/Understand Why It Does What It Does.					
Process Modeling/Design Tools.					

For the first element, *process scale-up, integration, and design for materials advances,* new processes will need to be developed. These processes will increase to commercial scale the quantity and quality of available advanced materials; or help incorporate these materials into new, revolutionary products based on a new material's properties. These scaled-up processes may be a next generation or an entirely new process. For example, forging ever-larger parts cannot be solved by building ever-larger forges (which becomes prohibitively expensive), but instead by developing new techniques such as partial forging.

New instrumentation and measurement capabilities also will be needed to support these new processes. These instruments will need to measure real-time process parameters such as the properties that provide the unique capabilities of the advanced materials (*e.g.,* composition). In addition, instruments for real-time inspection are needed to ensure and/or verify materials are being correctly incorporated into manufactured products that require the revolutionary functions of these new materials.

Proposals addressing *process scale-up, integration, and design for materials advances* will be considered responsive if they include scale-up of materials in one of the specified five materials classes (listed in Table 1) that are derived from biological or other sources and consist of one or more of the following:

• A single process to achieve the goals of the scale-up, or multiple processes integrated together into a coherent solution (*i.e.,* diverse processes

or multiples of a single process for "intensification");

• Scale-up of materials processes to manufacture and apply coatings that are within the scope requirements for the material types (nanomaterials; superalloys, alloys and smart materials; composites; ceramics; and glasses, including bulk metallic glasses); or

• Scale-up of materials processes for healthcare applications (*e.g.,* imaging, therapeutics, *etc.*).

Some examples of responsive proposals (not all-inclusive) include:

• Nano structured silica from rice plant or algae.

• Oxide nanoparticles produced by microorganisms.

• Quantum dot-based nanocomposites produced by genetically engineered viruses (*e.g.* M13 bacteriophage).

• Cellulose/polyethylene oxide nanocomposites produced by genetically engineered bacteria (Acetobacter Xylium).

• Biologically produced silver carbon composites for optically functional thin film.

• Biologically produced natural fiber reinforced aerogel composites.

• Composites made with chitosan derived from crustacean shells.

Proposals addressing *process scale-up, integration and design for materials advances* must address *all* of the following issues:

• Address one or more of the materials areas specified in this announcement.

• Quantify the baseline processing capabilities.

• Describe how the results of the process scale-up could lead to new products and manufacturing process capabilities.

• Provide quantification and qualification of the estimated output of the final project results.

• Scale-up of the quantities produced during the project must be targeted to increase by a factor of 1,000 fold or more (unit quantity per unit time) as compared to the baseline.

• A detailed scientific rationale and description of the challenges to accomplish scale-up of the process(es) must be included.

Proposals addressing *process scale-up, integration, and design of materials advances* will be considered more competitive if they:

• Include validation methodologies by or with processors or end users and/or

• Address sustainability issues.

Proposals addressing *process scale-up, integration, and design for materials advances* will be considered nonresponsive if they:

• Have the primary focus of the proposal on materials that are not included within Table 1 (*i.e.* pure polymers).

• Focus primarily on the application of material coatings using a material not included in Table 1.

• Do not provide a quantitative technical discussion of baseline capabilities (state-of-the-practice or state-of-the-art).

For the second element, *predictive modeling for materials advances and materials processing,* new tools are needed to enable researchers to use constitutive relations and rules (with validation) concerning the underlying behavior of materials (understanding structure vs. function) and the changes to behavior due to manufacturing processes. For example, new tools will need to account for the scale-dependent behavior of materials advances. This capability will enable a better and quicker understanding of why materials do what they do. These efforts will also enable extrapolation of that knowledge beyond the laboratory conditions for which they were developed, and will therefore need new validation and verification capabilities.

In addition, critical knowledge is needed about why certain decisions or assumptions were made, in order to incorporate new modeling capabilities for laboratory results into process design and modeling. Again, new validation and verification methodologies will be essential.

With successful development of these tools, processes, and technologies, the manufacturing communities will have significantly improved capabilities to quickly incorporate advanced materials breakthroughs into revolutionary products based on new materials functionality, and thus establish new competitive advantages in a global economy.

Proposals addressing *predictive modeling for materials advances and materials processing* must address *all* of the following issues:

• Address one or more of the materials areas given in Table 1.

• Quantify the baseline modeling capability.

• Describe how the results of the proposed modeling capabilities could lead to new products and manufacturing process capabilities.

Proposals for *predictive modeling for materials advances and materials processing* must also address *one or both* of the following:

• Develop constitutive relationships and rules that describe the behavior and the process of the materials at a level that is useful for describing laboratory results, as well as for developing a greater understanding of the materials for end users and/or

• Develop or use the constitutive relationships and rules to develop process design tools for the manufacturing processes for these materials advances.

Proposals addressing *predictive modeling for materials advances and materials processing* will be considered more competitive if they address:

• Collaboration by or with those who manufacture the materials, in order to validate the models and/or

• How users will specifically benefit from the acceleration and implementation of the proposed models in support of materials reliability (*i.e.* final properties or mechanical performance) and materials behavior before and after processing.

Proposals addressing *predictive modeling for materials advances and materials processing* that do not include validation of models will be considered less competitive.

Proposals addressing *predictive modeling for materials advances and materials processing* will be considered nonresponsive if they:

• Have the primary focus of the proposal on materials that are not included within Table 1 (*i.e.,* pure polymers).

• Focus primarily on the application of material coatings using a material not included under Table 1.

• Do not provide a quantitative technical discussion of baseline capabilities (state-of-the-practice or state-of-the-art).

The third element, *critical process advances,* requires modifications in manufacturing processes that augment and expand current limited capabilities. Applications could include those oriented towards the creation of novel methods to fabricate unique components from complex, difficult-to-machine materials (advanced engineering materials or smart materials), or the design and implementation of real-time, sensor-based, feedback-optimized systems for discrete, continuous or batch manufacturing processes. A discrete manufacturing example could be a process for making customized parts such as medical implants, using techniques such as additive manufacturing, near net-shape fabrication, or partial forging. Processes are needed for the manufacture of parts possessing complex geometries from existing and novel materials while preserving the properties of the material. A batch process example would be improved process monitoring

and *in situ* analytical tools, enabling a reduction in batch-to-batch variability and an improvement in quality, and quantity of biopharmaceuticals or other products produced in a more reliable and cost-effective manner.

A table for guidance on categorizing applicable processes and pathways to critical process advances is given below. TIP would expect solutions to the third societal challenge to map into one or more of the cells in Table 2 below.

TABLE 2

State-of-the-art approaches to critical manufacturing process advances for:	Process		
	Batch	Discrete	Continuous
Improving quality			
Increasing throughput			
Reducing costs			
Enhancing sustainability			
Enabling new capabilities			
Improving agility			
Other improvements			

Proposals addressing *critical process advances* will be considered responsive if they address improvements in quality, throughput, costs, sustainability, new capabilities, and agility, relative to the state-of-the-art for the process being proposed.

In drafting a proposal addressing *critical process advances* applicants should address topics in their area of interest such as:

• If a proposal offers improvements in several of these categories, the multiple improvements could be combined. For example, a proposed new process might offer half the setup time and triple the rate of production compared to existing processes.

• Benefits are not necessarily "linear"; for example, a component of a machine might benefit from increased strength or durability up to a point, beyond which there is little incremental benefit.

• Because manufacturing processes generally involve tradeoffs, a proposed new process may involve improvements in some areas and tradeoffs in other areas. For example, a proposed process might offer a factor of six cost reduction but a production rate decrease of a factor of two, and the net benefit of the tradeoff will be evaluated.

• Proposals should quantify to the extent possible every aspect of the advance in state of the art (as shown by the rows in the Table 2 above), including any that may offer decreased benefit as a tradeoff to further increase the advance in another area. Claimed benefits must be quantified for particular target application(s). (Example: "a new forging and heat treatment process for automobile axles will allow 50% lighter parts to be used and cut manufacturing cost by x%, improving fuel economy by y%, and ultimately reducing greenhouse gas emissions by z million tons per year.")

• The evaluation process should not make assumptions about performance parameters that are not discussed. For example, if a proposal claims lower cost but does not mention quality, reviewers will have to consider the possibility that quality is being sacrificed to save on cost, and such a proposal will be less competitive than one that offers comparable cost saving together with a claim for quality equal to or better than current products.

The term "biomanufacturing" as used throughout this notice and in the FFO announcement refers to manufacturing of biopharmaceuticals. Biopharmaceuticals are complex pharmaceutical products manufactured by biotechnology. Two types of biomanufacturing are considered: bioprocessing for production of biopharmaceuticals such as recombinant proteins as vaccines, therapeutics, or as molecular probes for diagnostics, and advanced biofabrication and processing for production of cell or tissue-based biopharmaceuticals such as engineered cells and engineered tissues as therapies. Engineered tissues are complex structures involving cells, scaffolds and signaling molecules. Manufacturing of either type of biopharmaceuticals is within the scope of the competition.

Proposals addressing *critical process advances* will be considered responsive if they provide improvements in one or more critical processes integrated together into a coherent solution to significantly enhance process efficiencies and reduce process variability.

Some examples of responsive proposals (not all-inclusive) include:

• New biomanufacturing process capabilities enabling rapid on-line monitoring of production cell health and function (*e.g.* cell viability, metabolism, contaminants) and on line monitoring of the structure and function of engineered cells or tissues when developed as therapeutics.

• Advanced bioprocesses for rapid on-line analysis of biopharmaceuticals (*e.g.* protein glycoforms, three-dimensional structure, aggregates, immunogenicity and contaminating bacteria, viruses, mycoplasma, production cell proteins and nucleic acids).

• Advanced active control feedback systems for monitoring and controlling complex bioprocesses and high throughput microreactor/bioreactor array systems for optimizing production cell systems (*e.g.* engineered Chinese Hamster Ovary or CHO cells, insect cells, microorganisms, or algae).

• Advances in critical processes in cost effective scale up of engineered cells or engineered tissues.

• New, automated processes for producing parts using composite materials.

• Affordable fabrication methods for lightweight components manufactured from low cost titanium powders.

• Reduction of energy intensity and demand, carbon dioxide and greenhouse gas emissions in glassmaking or other high energy consuming sectors.

• Precision additive manufacturing of medical devices.

• Low cost technologies for advancing the uses of nanomaterials in a variety of end products.

Responsive proposals addressing *critical process advances* must address *all* of the following issues:

• Address how the improved manufacturing processes are transformational compared to the state-of-the-art;

• Describe how the results of the research will lead to new and improved manufacturing processes enabling safe, cost effective and reliable production and new and improved products such as customized medical implants, large bearings, *etc.;*

• Describe why the technological solutions are high-risk and high-reward in nature; and

• Provide quantification and qualification of the estimated output of the final project results.

Proposals addressing *critical process advances* will be considered more competitive if they:

• Include multiple improvement areas from the table above;

• Include validation methodologies by or with processors or end users; and/or

• Address sustainability issues.

Examples of proposals addressing *critical process advances* that will be considered nonresponsive are:

• Any manufacturing process that offers only incremental improvement over existing processes;

• Processes that are intended primarily for military/weaponry applications (*e.g.* warhead manufacture, chemical/biological warfare materials production);

• Manufacturing processes that cannot be performed in the U.S. due to existing laws or regulations;

• Projects primarily focused on production of non engineered cells or tissues as therapeutics;

• Projects involving straightforward scale-up of biopharmaceuticals with incremental improvements in the manufacturing processes;

• Projects that involve incremental improvements in traditional processes for biomolecule production (*e.g.* vaccine production in chicken eggs, hormones such as insulin extracted from pig tissue);

• Biomanufacturing projects that primarily focus on processes for production of non-biopharmaceutical products (*e.g.* production of biofuels or small molecule drugs);

• Projects that primarily focus on drug discovery or design of new biomaterials;

• Projects that primarily focus on discovery of new production cell systems;

• Projects that use living genetically modified vertebrate animals, invertebrate animals, or plants as bioreactors for biopharmaceutical production;

• Production or scale up of scaffolds or biomaterials used in scaffold design that are not a part of the manufacturing of engineered tissues; and

• Projects with a primary focus (people, equipment, time, and/or funds) on device development.

Additional Requirements for All Manufacturing Proposals

TIP proposals are strengthened and generally considered most competitive when the proposed research plan includes validation by others of the research goals. When preparing a proposal, it is necessary to quantify and qualify the ability of the research results to "Transform the Nation's Capacity to Deal with Major Societal Challenges". The claims that any proposal makes relative to this key criterion are strengthened by validation of the research results with one or more end user(s) of the technology. The proposal may make assertions by narrative and referenced third-party documentation. The addition of "letters of interest" in the research results by potential end users adds strength to a proposal. Ultimately, the addition of one or more end users in a validation task implementing the research results would present the strongest case for commitment to the planned research goals.

Examples of validation tasks within each of the three elements might include:

• *Process scale-up, integration, and design for advanced materials:* Create a prototype using the advanced material produced from the research.

• *Predictive modeling for advanced materials and materials processing:* Apply modeling capability by implementing the new model information as a key knowledge component into a process or product.

• *Critical process advances:* Integrate the research results into processes for optimization, control and improvements in manufacturing and product analysis (*e.g.* composites, metals, chemicals, biopharmaceuticals).

Nonresponsive projects under this area of critical national need include:

• Projects whose principal focus is on discovery of new materials;

• Efforts related to the physical extraction of raw materials;

• Straightforward improvements to existing processes or materials without the potential for a transformational increase in performance to the technical requirements;

• Integration projects using only existing state-of-the-art processes, models or materials;

• Software development that is predominantly straightforward, routine data gathering using applications of standard software development practices; and

• Projects that do not include a quantitative baseline and quantitative metrics for tracking research.

In addition to the competition-specific nonresponsive projects, the following are nonresponsive projects:

• Straightforward improvements of existing products or product development.

• Projects that are Phase II, III, or IV clinical trials. TIP will rarely fund Phase I clinical trials and reserves the right not to fund a Phase I clinical trial. The portion of a Phase I trial that may be funded must be critical to meeting evaluation criterion (a)(1) addressing the scientific and technical merit of the proposal. The trial results must be essential for completion of a critical R&D task of the project. The definitions of all phases of clinical trials are provided in the TIP Guidelines and Documentation Requirements for Research Involving Human & Animal Subjects located at *http://www.nist.gov/tip/helpful-resources.cfm.*

• Pre-commercial-scale demonstration projects where the emphasis is on demonstrating that some technology works on a large scale or is economically sound rather than on R&D that advances the state of the art and is high-risk, high-reward.

• Projects that TIP determines would likely be completed without TIP funds in the same time frame or nearly the same time frame, or with the same scale or scope.

• Predominantly straightforward, routine data gathering (*e.g.,* creation of voluntary consensus standards, data gathering/handbook/specification sheet preparation, testing of materials, or unbounded research aimed at basic discovery science) or application of standard engineering practices.

• Projects in which the predominant risk is market oriented—that is, the risk that the end product may not be embraced by the marketplace.

• Projects with software work, that are predominantly about final product details and product development, and that have significant testing involving users outside the research team to determine if the software meets the original research objectives, are likely to be either uncompetitive or possibly ineligible for funding. However, R&D projects with limited software testing, involving users outside of the research team, or vertebrate animals, may be eligible for funding and contain eligible costs within a TIP award when the testing is critical to meeting evaluation criteria and/or award criteria and the testing results are essential for completion of a critical task in the proposed research. This type of testing in projects may also be considered to involve human subjects or vertebrate animals in research and require compliance with applicable Federal regulations and NIST policies for the

protection of human subjects or live vertebrate animals.

Unallowable/Ineligible Costs: The following items, regardless of whether they are allowable under the Federal cost principles, are ineligible/unallowable under TIP:

a. Bid and proposal costs unless they are incorporated into a Federally-approved indirect cost rate (*e.g.,* payments to any organization or person retained to help prepare a proposal).

b. Construction costs for new buildings or extensive renovations of existing buildings. However, costs for the construction of experimental research and development facilities to be located within a new or existing building are allowable provided the equipment or facilities are essential for carrying out the proposed project and are approved in advanced by the NIST Grants Officer. These types of facility costs may need to be prorated if they will not be used exclusively for the research activities proposed.

c. Contractor office supplies and contractor expenses for conferences/workshops.

d. Contracts to another part of the same company or to another company with identical or nearly identical ownership. Work proposed by another part of the same company or by another company with identical or nearly identical ownership should be shown as funded through inter-organizational transfers that do not contain profit. Inter-organizational transfers should be broken down in the appropriate budget categories.

e. For research involving human and/or animal subjects, any costs used to secure Institutional Review Board or Institutional Animal Care and Use Committee approvals before or during the award.

f. General purpose office equipment and supplies that are not used exclusively for the research: *e.g.,* office computers, printers, copiers, paper, pens, and toner cartridges.

g. Indirect costs, which must be absorbed by the recipient. However, indirect costs are allowable for contractors under a single company or joint venture. (Note that indirect costs absorbed by the recipient may be used to meet the cost-sharing requirement.)

h. Marketing, sales, or commercialization costs, including marketing surveys, commercialization studies, and general business planning, unless they are included in a Federally approved indirect cost rate.

i. Office furniture costs, unless they are included in a Federally approved indirect cost rate.

j. Patent costs and legal fees, unless they are included in a Federally approved indirect cost rate.

k. *Preaward costs: i.e.,* any costs incurred prior to the award start date.

l. Profit, management fees, interest on borrowed funds, or facilities capital cost of money. However, profit is allowable for contractors under a single company or joint venture.

m. Project development planning (*e.g.* patent and literature searches) and creation of milestones. For example, proposals that plan on developing milestones only if an award is received and after literature searches are performed under the award are generally not competitive. Costs for literature searches in general are ineligible.

n. Relocation costs, unless they are included in a Federally approved indirect cost rate.

o. *Salaries:* NIST limits the salaries of project personnel to not exceed Level I of the Executive Schedule ($199,700 as of January 2010 *http://www.opm.gov/oca/10tables/html/ex.asp*).

p. Tuition costs are generally not allowed as direct costs on projects. An institution of higher education participating in a TIP project as a contractor or as a joint venture member or lead may charge TIP for tuition remission or other forms of compensation paid as, or in lieu of, wages to students performing necessary work. These are allowable, provided the requirements are met under 2 CFR Subtitle A, Chapter 2, Part 220, Appendix A. 45 (formerly OMB Circular A–21, Section J. 41). In such cases, tuition remission and other forms of compensation paid to students shall be treated as direct costs in accordance with the actual work being performed, and listed in the budget under "Other." Tuition remission may be charged on an average rate basis.

Funding Availability: Fiscal year 2010 appropriations include funds in the amount of approximately $25 million for new TIP awards. The anticipated start date is January 1, 2010. The period of performance depends on the R&D activity proposed. A single company can receive up to a total of $3 million with a project period of performance of up to 3 years. A joint venture can receive up to total of $9 million with a project period of performance of up to 5 years. Continuation funding after the initial award is based on satisfactory performance, availability of funds, continued relevance to program objectives, and is at the sole discretion of NIST.

Eligibility: Single companies and joint ventures may apply for TIP funding as provided in 15 CFR §§ 296.2, 296.4, and 296.5. Nonprofit organizations must meet the eligibility criteria set forth in 15 CFR 296.5(a)(2), which explains the eligibility criteria for companies.

Large-sized Company Participation: A large-sized company is not eligible to apply for TIP funding. A large-sized company is defined as any business, including any parent company plus related subsidiaries, having annual revenues in excess of $1.7208 billion. This number is based on the May 2009 issue of *Fortune* magazine's Fortune 1000 list. (Note that the revenue amount will be updated annually and will be noted in future annual announcements of availability of funds.)

Cost-Sharing Requirements: Proposers must provide a cost share of at least 50 percent of the yearly total project costs (direct plus all of the indirect costs).

Evaluation and Award Criteria: Proposals are selected for funding based on the evaluation criteria listed in 15 CFR 296.21 and the award criteria listed in 15 CFR 296.22 as identified below. Additionally, pursuant to 15 U.S.C. 278n(c), no proposal will be funded unless TIP determines that it meets all of the award criteria listed in 15 CFR 296.22. Detailed guidance on how to address the evaluation and award criteria is provided in Chapter 2 of the TIP Proposal Preparation Kit, which is available at *http://www.nist.gov/tip/helpful-resources.cfm.*

Evaluation Criteria: The two components of the evaluation criteria and respective weights as listed in 15 CFR 296.21 are as follows:

(a)(1) The proposer(s) adequately addresses the scientific and technical merit and how the research may result in intellectual property vesting in a United States entity including evidence that:

(i) The proposed research is novel;

(ii) The proposed research is high-risk, high-reward;

(iii) The proposer(s) demonstrates a high level of relevant scientific/technical expertise for key personnel, including contractors and/or informal collaborators, and has access to the necessary resources, for example research facilities, equipment, materials, and data, to conduct the research as proposed;

(iv) The research result(s) has the potential to address the technical needs associated with a major societal challenge not currently being addressed; and

(v) The proposed research plan is scientifically sound with tasks, milestones, timeline, decision points and alternate strategies.

(2) Total weight of (a)(1)(i) through (v) is 50%.

(b)(1) The proposer(s) adequately establishes that the proposed research has strong potential for advancing the state-of-the-art and contributing significantly to the United States science and technology knowledge base and to address areas of critical national need through transforming the Nation's capacity to deal with a major societal challenge(s) that is not currently being addressed, and generate substantial benefits to the Nation that extend significantly beyond the direct return to the proposer including an explanation in the proposal:

(i) Of the potential magnitude of transformational results upon the Nation's capabilities in an area;

(ii) Of how and when the ensuing transformational results will be useful to the Nation; and

(iii) Of the capacity and commitment of each award participant to enable or advance the transformation to the proposed research results (technology).

(2) Total weight of (b)(1)(i) through (iii) is 50%.

Award Criteria: The six components of the award criteria as listed in 15 CFR 296.22 are as follows:

(a) The proposal explains why TIP support is necessary, including evidence that the research will not be conducted within a reasonable time period in the absence of financial assistance from TIP;

(b) The proposal demonstrates that reasonable and thorough efforts have been made to secure funding from alternative funding sources and no other alternative funding sources are reasonably available to support the proposal;

(c) The proposal explains the novelty of the research (technology) and demonstrates that other entities have not already developed, commercialized, marketed, distributed, or sold similar research results (technologies);

(d) The proposal has scientific and technical merit and may result in intellectual property vesting in a United States entity that can commercialize the technology in a timely manner;

(e) The proposal establishes that the research has strong potential for advancing the state-of-the-art and contributing significantly to the United States science and technology knowledge base; and

(f) The proposal establishes that the proposed transformational research (technology) has strong potential to address areas of critical national need through transforming the Nation's capacity to deal with major societal challenges that are not currently being addressed, and generate substantial benefits to the Nation that extend significantly beyond the direct return to the proposer.

NIST must determine that a proposal successfully meets all six award criteria for the proposal to receive funding under the Program.

Selection Factors: In making final selections, the Selecting Official will select funding recipients based upon the Evaluation Panel's rank order of the proposals and the following selection factors:

a. Appropriate distribution of funds among technologies and their applications,

b. Availability of funds, and/or

c. Program priorities.

Program Priorities: TIP is soliciting proposals under this fiscal year 2010 competition in the area of critical national need entitled "Manufacturing" as described in the Program Description section above.

Selection Procedures: Proposals are selected based on a multi-disciplinary peer-review process, as described in 15 CFR 296.20. A preliminary review is conducted to determine if the proposal is in accordance with 15 CFR 296.3; complies with the eligibility requirements described in 15 CFR 296.5; addresses award criteria (a) through (c) of 15 CFR 296.22; was submitted to a previous TIP competition, and if so, has been substantially revised; and is complete. Proposals that are incomplete or do not meet any one of the preliminary review requirements will normally be eliminated. All remaining proposals are then carefully reviewed by an Evaluation Panel consisting of Federal employees using the TIP evaluation criteria listed in 15 CFR 296.21 and award criteria listed in 15 CFR 296.22. The Evaluation Panel will present funding recommendations to the Selecting Official in rank order for further consideration. The Selecting Official makes the final selections for funding. The selection of proposals by the Selecting Official is final and cannot be appealed. The final approval of selected proposals and award of assistance will be made by the NIST Grants Officer. The award decision of the NIST Grants Officer is final and cannot be appealed.

NIST reserves the right to negotiate the cost and scope of the proposed work with the proposers that have been selected to receive awards. This may include requesting that the proposer delete from the scope of work a particular task that is deemed by NIST to be inappropriate for support. NIST also reserves the right to reject a proposal where information exists that raises a reasonable doubt as to the responsibility of the proposer.

Intellectual Property Requirements: For single company award recipients, pursuant to the Bayh-Dole Act (35 U.S.C. 202(a) and (b)) and "Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy" (February 18, 1983), the entity that invents owns the invention. However, pursuant to 35 U.S.C. 202(a)(i), when a single company or its contractor under a TIP award is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, NIST will require that title to inventions made by such parties be transferred to a United States entity that will ensure the commercialization of the technology in a timely fashion.

For joint ventures, ownership of inventions arising from a TIP-funded project may vest in any participant in a joint venture, as agreed by the members of the joint venture (notwithstanding 35 U.S.C. 202(a) and (b)). (Participant includes any entity that is identified as a recipient, subrecipient, or contractor on an award to a joint venture.)

Title to any such invention shall not be transferred or passed, except to a participant in the joint venture, until the expiration of the first patent obtained in connection with such invention.

Should the last existing participant in a joint venture cease to exist prior to the expiration of the first patent obtained in connection with any invention developed from assistance provided under TIP, title to such patent must be transferred or passed to a U.S. entity that can commercialize the technology in a timely fashion.

The United States reserves a nonexclusive, nontransferable, irrevocable paid-up license, to practice or have practiced for or on behalf of the United States any intellectual property developed from a TIP award. The Federal government shall not in the exercise of such license publicly disclose proprietary information related to the license. This does not prohibit the licensing to any company of intellectual property rights arising from a TIP-funded project. (15 CFR 296.11(b)(3)). The Federal government also has march-in rights in accordance with 37 CFR 401.6. *Intellectual property* means an invention patentable under title 35, United States Code, or any patent on such an invention, or any work for which copyright protection is available under title 17, United States Code. (15 CFR 296.2.)

Projects Involving Human Subjects. Research involving human subjects

must be in compliance with applicable Federal regulations and NIST policies for the protection of human subjects. Human subjects research activities involve interactions with live human subjects or the use of data, images, tissue, and/or cells/cell lines (including those used for control purposes) from human subjects. Research involving human subjects may include activities such as the use of image and/or audio recording of people, taking surveys or using survey data, using databases containing personal information, testing software with volunteers, and many tasks beyond those within traditional biomedical research. A Human Subjects Determination Checklist is included in the April 2010 TIP Proposal Preparation Kit in Chapter 6 (*http://www.nist.gov/tip/helpful-resources.cfm*) to assist you in determining whether your proposed research plan has human subjects involvement, which would require additional information in your proposal submission, and possibly more documentation during the Evaluation Panel's consideration of your proposal. *See* the *TIP Guidelines and Documentation Requirements for Research Involving Human & Animal Subjects* for more specific information on documentation requirements and due dates for documentation located at *http://www.nist.gov/tip/helpful-resources.cfm* or by calling 1–888–847–6478. President Obama has issued Exec. Order No. 13,505, 74 FR 10667 (March 9, 2009), revoking previous executive orders and Presidential statements regarding the use of human embryonic stem cells in research. On July 30, 2009, President Obama issued a memorandum directing that agencies that support and conduct stem cell research adopt the "National Institutes of Health Guidelines for Human Stem Cell Research" (NIH Guidelines), which became effective on July 7, 2009, "to the fullest extent practicable in light of legal authorities and obligations." On September 21, 2009, the Department of Commerce submitted to the Office of Management and Budget a statement of compliance with the NIH Guidelines. In accordance with the President's memorandum, the NIH Guidelines, and the Department of Commerce statement of compliance, NIST will support and conduct research using only human embryonic stem cell lines that have been approved by NIH in accordance with the NIH Guidelines and will review such research in accordance with the Common Rule and NIST implementing procedures, as appropriate. NIST will not support or conduct any type of research that the NIH Guidelines prohibit NIH from funding. NIST will follow any additional polices or guidance issued by the current Administration on this topic.

Projects Involving Live Vertebrate Animals. Research involving live vertebrate animals must be in compliance with applicable Federal regulations and NIST policies for the protection of live vertebrate animals. Vertebrate animal research involves live animals that are being cared for, euthanized, or used by the project participants to accomplish research goals or for teaching or testing. The regulations do not apply to animal tissues purchased from commercial processors or tissue banks or to uses of preexisting images of animals (*e.g.,* a wildlife documentary or pictures of animals in newscasts). The regulations do apply to any animals that are transported, cared for, euthanized or used by a project participant for testing, research, or training such as testing of new procedures or projects, collection of biological samples or observation data on health and behavior. Detailed information regarding the use of live vertebrate animals in research plans and required documentation is available in the *TIP Guidelines and Documentation Requirements for Research Involving Human & Animal Subjects* located at *http://www.nist.gov/tip/helpful-resources.cfm* or by calling 1–888–847–6478.

Executive Order 12372 (Intergovernmental Review of Federal Programs): Proposals under this program are not subject to Executive Order 12372.

Administrative Procedure Act and Regulatory Flexibility Act: Prior notice and comment are not required under 5 U.S.C. 553, or any other law, for rules relating to public property, loans, grants, benefits or contracts (5 U.S.C. 553(a)). Because prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

E.O. 13132 (Federalism): This notice does not contain policies with Federalism implications as defined in Executive Order 13132.

E.O. 12866 (Regulatory Planning and Review): This notice is determined to be not significant under Executive Order 12866.

Paperwork Reduction Act: Notwithstanding any other provision of the law, no person is required to, nor shall any person be subject to penalty for failure to, comply with a collection of information, subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This notice contains collection-of-information requirements subject to the PRA. The use of Form NIST–1022, Standard Form-424 (R&R), SF–424B, SF–LLL, Research and Related Other Project Information Form, and CD–346 has been approved by OMB under the respective control numbers 0693–0050, 4040–0001, 4040–0007, 0348–0046, 4040–0001, and 0605–0001.

Administrative and National Policy Requirements. DoC Pre-Award Notification Requirements. The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements are contained in, 73 FR 7696 (February 11, 2008), apply to this notice. On the form SF–424 R&R items 5. and 6., the applicant's 9-digit Employer/Taxpayer Identification Number (EIN/TIN) and 9-digit Dun and Bradstreet Data Universal Numbering System (DUNS) number must be consistent with the information on the Central Contractor Registration (CCR) (*http://www.ccr.gov*) and Automated Standard Application for Payment System (ASAP). For complex organizations with multiple EIN/TIN and DUNS numbers, the EIN/TIN and DUNS number MUST be the numbers for the applying organization. Organizations that provide incorrect/inconsistent EIN/TIN and DUNS numbers may experience significant delays in submitting their proposals through grants.gov and receiving funds if their proposal is selected for funding.

Dated: April 13, 2010.

Marc G. Stanley,

Acting Deputy Director.

[FR Doc. 2010–8954 Filed 4–16–10; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–936]

Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China: Correction to Notice of Amended Final Determination Pursuant to Final Court Decision

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* April 19, 2010.

FOR FURTHER INFORMATION CONTACT: John Conniff, AD/CVD Operations, Office 3,

Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Room 4014, Washington, DC 20230; telephone: (202) 482–1009.

SUPPLEMENTARY INFORMATION:

Correction

On March 31, 2010, the Department of Commerce ("the Department") published a notice of amended final determination pursuant to final court decision for circular welded carbon quality steel line pipe from the People's Republic of China. *See Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China: Notice of Amended Final Determination Pursuant to Final Court Decision*, 75 FR 16071 (March 31, 2010) ("Court Amended Final Determination"). Subsequent to the publication of the notice in the **Federal Register**, we identified an inadvertent error.

The *Court Amended Final Determination* states that the rate for the Huludao Companies (Huludao Seven Star Group, Huludao Steel Pipe Industrial Co. Ltd., and Huludao Bohai Oil Pipe Industrial Co. Ltd.), the respondent, is 33.00 percent when it should be 33.43 percent. Additionally it states that the All Others Rate is 36.53 percent when it should be 36.74 percent. These were both typographical errors.

This notice is published in accordance with sections 777(i) and 705(d) of the Tariff Act of 1930, as amended.

Dated: April 13, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010–8992 Filed 4–16–10; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–943]

Certain Oil Country Tubular Goods from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, Affirmative Final Determination of Critical Circumstances and Final Determination of Targeted Dumping

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* April 19, 2010.

SUMMARY: On November 17, 2009, the Department of Commerce (the "Department") published its notice of preliminary determination of sales at less than fair value ("LTFV") and affirmative preliminary determination of critical circumstances in the antidumping investigation of certain oil country tubular goods ("OCTG") from the People's Republic of China ("PRC").[1] The period of investigation ("POI") is October 1, 2008, through March 31, 2009. We invited interested parties to comment on our preliminary determination of sales LTFV and the post–preliminary memoranda. Based on our analysis of the comments received, we have made changes to our calculations for the mandatory respondents. We determine that OCTG from the PRC are being, or are likely to be, sold in the United States at LTFV as provided in section 735 of the Tariff Act of 1930, as amended ("the Act"). The estimated margins of sales at LTFV are shown in the "Final Determination Margins" section of this notice.

FOR FURTHER INFORMATION CONTACT: Paul Stolz or Eugene Degnan, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–4474 or (202) 482–0414, respectively.

SUPPLEMENTARY INFORMATION:

Case History

The Department published its Preliminary Determination on November 17, 2009. The Department subsequently issued a ministerial error allegation memorandum, in which it agreed to correct several ministerial errors.[2] On December 30, 2009, pursuant to the correction of ministerial errors, the Department published an amended preliminary determination.[3]

Between December 7, 2009, and December 18, 2009, the Department conducted verifications of Jiangsu Changbao Steel Tube Co., Ltd. and Jiangsu Changbao Precision Tube Co., Ltd. (collectively "Changbao"), and Tianjin Pipe (Group) Corp. and Tianjin International Economic and Trading Corp. (collectively "TPCO"). *See* the "Verification" section below for additional information.

On February 22, 2010, TMK IPSCO, V&M Star L.P., V&M TCA, Wheatland Tube Corp., Evraz Rocky Mountain Steel, and the United States Steel Workers (collectively, "Petitioners") filed a submission with the Department including an affidavit by a V&M Star L.P. official attesting that V&M Star L.P. obtained and tested certain OCTG produced and exported by Changbao with the corresponding mill test certificate allegedly issued by Changbao. On March 4, 2010, Changbao filed a submission which it asserted included all laboratory test reports for all of the relevant OCTG addressed in Petitioners' February 22, 2010 submission, to all customers, in all markets for the period of July 2008, through April 2009. The Department determined to accept both of these submissions.[4]

On March 2, 2010, the Department issued a memorandum regarding the affiliations of TPCO in this investigation.[5] On March 2, 2010, the Department issued a memorandum addressing the targeted dumping allegation made by Petitioners in this investigation.[6] Additionally, on March 9, 2010, we released certain U.S. Customs and Border Protection ("CBP") information regarding entry documentation for sales of OCTG made by Changbao.[7] On March 23, 2010, the Department released a Dunn & Bradstreet report related to the ownership of a TPCO affiliate and, on March 24, 2010, Petitioners also placed on the record a Dunn & Bradstreet report relating to the ownership of a TPCO affiliate. Also on March 25, 2010, Changbao submitted a document containing lab tests of its OCTG. We retained all of this information on the record.

We invited interested parties to comment on the *Preliminary Determination*, and the post–preliminary affiliation and Targeted

[1] *See Certain Oil Country Tubular Goods From the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value, Affirmative Preliminary Determination of Critical Circumstances and Postponement of Final Determination*, 74 FR 59117 (November 17, 2009) ("*Preliminary Determination*").

[2] *See* Memorandum entitled "Ministerial Error Memorandum, Certain Oil Country Tubular Goods from the People's Republic of China, Preliminary Determination of Sales at Less Than Fair Value," dated December 3, 2009.

[3] *See Certain Oil Country Tubular Goods From the People's Republic of China: Notice of Amended Preliminary Determination of Sales at Less Than Fair Value*, 74 FR 69065 (December 30, 2009) ("*Amended Preliminary Determination*").

[4] *See* Memorandum regarding Resubmission of Comments on Surrogate Values by Jiangsu Changbao Steel Tube Co., Ltd. to the Department of Commerce, dated March 3, 2010.

[5] *See* Memorandum regarding OCTG from the PRC: Tianjin Pipe (Group) Co. Affiliations, dated March 2, 2010 ("TPCO Affiliation Memo").

[6] *See* Memorandum regarding Certain Oil Country Tubular Goods from the People's Republic of China: Targeted Dumping – Jiangsu Changbao Steel Tube Co., Ltd. and Jiangsu Changbao Precision Steel Tube Co., Ltd. and Tianjin Pipe (Group) Co., dated March 2, 2010 ("Targeted Dumping Memo").

[7] *See* Memorandum regarding Certain Oil Country Tubular Goods from the People's Republic of China: Release of Customs and Border Patrol Data, dated March 9, 2010 ("Changbao CBP information").

Dumping Memo. Additionally, we invited interested parties to comment on, and submit new factual rebuttal information regarding, the Changbao CBP information. On March 9, 2010, multiple interested parties filed case briefs with respect to the *Preliminary Determination*, the TPCO Affiliation Memo and the Targeted Dumping Memo. On March 11, 2010, many of these same parties filed case briefs and new factual rebuttal information regarding the Changbao CBP information. These same parties filed rebuttal briefs on March 15, 2010. The Department held a public hearing on March 26, 2010.

Tolling of Administrative Deadlines

As explained in the memorandum from the Deputy Assistant Secretary for Import Administration, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from February 5, through February 12, 2010. Thus, all deadlines in this segment of the proceeding have been extended by seven days. The revised deadline for this final determination is now April 8, 2010. *See* Memorandum to the Record from Ronald Lorentzen, DAS for Import Administration, regarding "Tolling of Administrative Deadlines As a Result of the Government Closure During the Recent Snowstorm," dated February 12, 2010.

Verification

As provided in section 782(i) of the Act, we conducted verification of the information submitted by TPCO and Changbao for use in our final determination. *See* the Department's verification reports on the record of this investigation in the Central Records Unit ("CRU"), Room 1117 of the main Department building, with respect to these entities. We used standard verification procedures, including examination of relevant accounting and production records, as well as original source documents provided by respondents.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this investigation are addressed in the "Investigation of Certain Oil Country Tubular Goods from the People's Republic of China: Issues and Decision Memorandum," dated concurrently with this notice and which is hereby adopted by this notice ("Issues and Decision Memorandum"). A list of the issues which parties raised and to which we respond in the Issues and Decision Memorandum is attached to this notice as Appendix I. The Issues and Decision Memorandum is a public document and is on file in the CRU, and is accessible on the Web at ia.ita.doc.gov/frn. The paper copy and electronic version of the memorandum are identical in content.

Changes Since the Preliminary Determination

Based on our analysis of information on the record of this investigation, we have made the following changes:

Surrogate Financial Ratios

- For the final determination we have calculated surrogate financial ratios using the fiscal year 2008–2009 financial statements of three Indian pipe producers: Indian Seamless Metal Tubes Limited; Oil Country Tubular Ltd.; and Tata Steel Limited. *See* Issues and Decision Memorandum at Comment 13.
- We have made several corrections to the calculation of the surrogate financial ratios. See Final SV Memo.[8]

Company–Specific Changes Since the Preliminary Determination

TPCO

- For the final determination, we have calculated TPCO's inputs of iron ore pellets using its market economy purchase price for this factor. *See* Issues and Decision Memorandum at Comment 24.
- For the final determination, we have determined to value TPCO's billets with data from Indonesia HTS category 7207.20.100. *See* Issues and Decision Memorandum at Comment 20.
- For the final determination, we have applied partial adverse facts available ("AFA") for merchandise TPCO shipped to Company B, which the Department finds is an affiliate of TPCO. *See* Issues and Decision Memorandum at Comment 31.
- For the final determination, we have determined to omit transportation costs for TPCO's inputs of water. *See* Issues and Decision Memorandum at Comment 14.
- For the final determination, we have valued TPCO's inputs of natural gas using Gas Authority of India, Ltd. prices inflated to the POI. *See* Issues and Decision Memorandum at Comment 25.
- For the final determination, we have valued microchromium and ferrochromium using Indian HTS subheadings 7202.4900 and 7202.4100, respectively. *See* Issues and Decision Memorandum at Comment 26.
- For the final determination, we have recalculated the surrogate value for iron ore powder by taking a simple average of two sets of financial statements from Indian pig iron producers, Kirloskar Ferrous Industries Limited and KIOCL Limited. *See* Issues and Decision Memorandum at Comment 27.
- For the final determination, we have valued oxygen and nitrogen based on surrogate values derived from the financial statements of Bhoruka Gas, Ltd. *See* Issues and Decision Memorandum at Comment 28.
- For the final determination, the Department separately valued domestic inland insurance for TPCO's U.S. sales. *See* Issues and Decision Memorandum at Comment 3.
- For the final determination, as partial AFA, we have valued TPCO's self–produced, as well as its purchased, compressed air. Because TPCO removed the consumption figures for the purchased compressed air from its factors of production ("FOP") database, we applied as the consumption rate the highest (originally) reported consumption rate for any product, and calculated cost based on the electricity consumption required to produce that highest consumption rate of compressed air. *See* Issues and Decision Memorandum at Comment 22.
- In the *Preliminary Determination* we valued truck freight for water in the calculation of normal value because TPCO reported truck freight for water in its FOP database. For the final determination, we have determined that TPCO did not incur truck freight for water and have not included a value for truck freight for water in the normal value calculation. See Issues and Decision Memorandum at Comment 14.
- For the final determination we have adjusted TPCO's reported U.S. gross price for sales tax incurred in the United States to ensure that the gross price value would reflect the actual invoice price because TPCO reported a value for gross price that reflected the invoice price plus U.S. sales tax. *See* Issues and Decision Memorandum at Comment 12.
- Based on verification findings, for the final determination we are valuing lump ore using a surrogate

[8] Memorandum from Sergio Balbontin, through Eugene Degnan regarding: Investigation of Certain Oil Country Tubular Goods from the People's Republic of China: Surrogate Values Memorandum for the Final Results, dated April 8, 2010 ("Final SV Memo")

value. Lump ore was valued at the *Preliminary Determination* using market economy purchase prices.

- Based on verification findings, for the final determination, we are valuing pellets using market economy purchase prices. Pellets were valued at the *Preliminary Determination* using a surrogate value.

- For the *Preliminary Determination*, World Trade Atlas ("WTA") data was available for only the first five months of the POI, October 2008 through February 2009. Therefore, for surrogate values calculated for the *Preliminary Determination* using WTA data, we relied on data from only five months of the POI. For the final determination, WTA data covering the full POI is available. Therefore, for surrogate values calculated for the final determination derived from WTA data, we have relied on WTA data covering the full POI.

Changbao

- For the final determination, we are denying Changbao a separate rate and, accordingly, have assigned Changbao the PRC–wide entity rate of 99.14 percent. *See* Issues and Decision Memorandum at Comment 30, *see also* Memorandum from Eugene Degnan, through Wendy Frankel regarding: Application of Total Adverse Facts Available for Changbao Steel Tube Co. and Jiangsu Changbao Precision Steel Tube Co., Ltd. in the Antidumping Duty Investigation of Oil Country Tubular Goods from the People's Republic of China, dated April 8, 2010 ("Changbao AFA Memo").
- For the final determination, because Changbao is part of the PRC–wide entity, we have suspended liquidation of entries exported by Changbao, and determined that critical circumstances apply to Changbao's U.S. sales.

Scope of Investigation

The merchandise covered by the investigation consists of certain OCTG, which are hollow steel products of circular cross–section, including oil well casing and tubing, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.*, whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute ("API") or non–API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of the investigation also covers OCTG coupling stock. Excluded from the scope of the investigation are casing or tubing containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise covered by the investigation is currently classified in the Harmonized Tariff Schedule of the United States ("HTSUS") under item numbers: 7304.29.10.10, 7304.29.10.20, 7304.29.10.30, 7304.29.10.40, 7304.29.10.50, 7304.29.10.60, 7304.29.10.80, 7304.29.20.10, 7304.29.20.20, 7304.29.20.30, 7304.29.20.40, 7304.29.20.50, 7304.29.20.60, 7304.29.20.80, 7304.29.31.10, 7304.29.31.20, 7304.29.31.30, 7304.29.31.40, 7304.29.31.50, 7304.29.31.60, 7304.29.31.80, 7304.29.41.10, 7304.29.41.20, 7304.29.41.30, 7304.29.41.40, 7304.29.41.50, 7304.29.41.60, 7304.29.41.80, 7304.29.50.15, 7304.29.50.30, 7304.29.50.45, 7304.29.50.60, 7304.29.50.75, 7304.29.61.15, 7304.29.61.30, 7304.29.61.45, 7304.29.61.60, 7304.29.61.75, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.29.10.30, 7306.29.10.90, 7306.29.20.00, 7306.29.31.00, 7306.29.41.00, 7306.29.60.10, 7306.29.60.50, 7306.29.81.10, and 7306.29.81.50.

The OCTG coupling stock covered by the investigation may also enter under the following HTSUS item numbers: 7304.39.00.24, 7304.39.00.28, 7304.39.00.32, 7304.39.00.36, 7304.39.00.40, 7304.39.00.44, 7304.39.00.48, 7304.39.00.52, 7304.39.00.56, 7304.39.00.62, 7304.39.00.68, 7304.39.00.72, 7304.39.00.76, 7304.39.00.80, 7304.59.60.00, , 7304.59.80.15, 7304.59.80.20, 7304.59.80.25, 7304.59.80.30, 7304.59.80.35, 7304.59.80.40, 7304.59.80.45, 7304.59.80.50, 7304.59.80.55, 7304.59.80.60, 7304.59.80.65, 7304.59.80.70, and 7304.59.80.80.

The HTSUS subheadings are provided for convenience and customs purposes only, the written description of the scope of the investigation is dispositive.

In accordance with the preamble to our regulations, we set aside a period of time for parties to raise issues regarding product coverage and encouraged all parties to submit comments within 20 calendar days of publication of the *Initiation Notice*.[9] We received no comments from interested parties on issues related to the scope.

Targeted Dumping

We have analyzed the case and rebuttal briefs with respect to targeted dumping issues submitted for the record in this investigation. As a result of our analysis, the Department finds that TPCO engaged in targeted dumping. We determine that the standard average–to-average comparison methodology does not account for the identified pattern of price differences. Accordingly, we have applied the alternative average–to-transaction to all sales to calculate the dumping margin for TPCO. For further discussion, see Issues and Decision Memorandum at Comment 2.

Shorter Cost–Averaging Periods

On May 22, 2009, Petitioners alleged that OCTG prices, and the cost of raw material inputs used to produce subject merchandise, decreased dramatically during the POI.[10] Petitioners claimed that in similar instances in other proceedings, the Department has used shorter cost–averaging periods when calculating normal value (*i.e.*, the Department calculated cost of production or constructed values on a quarterly basis for comparison to sales prices, rather than using a POI or period of review ("POR") average).[11] Accordingly, Petitioners requested that the Department require respondents to report their material input usage rates on a monthly basis for both the POI and the six months preceding the POI, and that the Department calculate normal value using monthly consumption periods and monthly surrogate values rather than a POI–average of inputs and surrogate values.

The Department stated in the *Preliminary Determination* that the Department has not considered using shorter cost–averaging periods in non

[9] *See Antidumping Duties; Countervailing Duties; Final Rule*, 62 FR 27296 27323 (May 19, 1997); *see also Oil Country Tubular Goods From the People's Republic of China: Initiation of Antidumping Duty Investigations*, 72 FR 20671, 20672 (May 5, 2009) ("*Initiation Notice*").

[10] *See* Petitioners' Letter to the Department: Certain Oil Country Tubular Goods from the People's Republic of China: Request that the Department Collect Additional Data from the Respondents (May 22, 2009)

[11] *See* 19 CFR 351.414(d)(3): Time period over which weighted average is calculated. When applying the average-to-average method, the Secretary normally will calculate weighted averages for the entire period of investigation or review, as the case may be. However, when normal values, export prices, or constructed export prices differ significantly over the course of the period of investigation or review, the Secretary may calculate weighted averages for such shorter period as the Secretary deems appropriate.

market–economy ("NME") cases, but only in market–economy ("ME") cases where we determine that actual production costs changed significantly during the POI/POR, and where there was evidence of a linkage between the actual cost changes and the sales prices in a given POI/POR.[12] We further stated that in an NME context, except in limited circumstances when inputs are purchased from ME suppliers, the Department calculates normal value using surrogate values in lieu of actual input costs and, thus, because the use of the shorter cost–averaging periods would not more accurately reflect experience of the respondent operating in the NME during the period under examination, we would continue to base costs on POI–average surrogate values rather than the shorter cost–averaging periods for the *Preliminary Determination*.

We further stated that it is not clear how the shorter cost–averaging period methodology employed in ME cases can fit methodologically or analytically in an NME context, and we invited parties to comment on these issues and on what facts would warrant the use of shorter cost–averaging periods in this case for the final determination.

Both in a January 22, 2010, submission, and in their case briefs, Petitioners argue that the Department should use shorter cost–averaging periods to calculate the margin for Changbao. Petitioners argue that both the significance aspect and the linkage aspect of the Department's analysis regarding the use of shorter cost–averaging periods are met in regards to Changbao. Petitioners did not, however, address the Department's concerns, expressed in the *Preliminary Determination*, regarding how the shorter cost–averaging period methodology can appropriately be applied in the context of an NME case. Neither the January 22, 2010 submission nor the case briefs argued for the use of shorter cost–averaging periods to calculate the margin for TPCO. Accordingly, because the Petitioners' only argue that the Department should apply the shorter cost–averaging methodology to Changbao, and we have determined that Changbao is not entitled to a separate rate in the investigation, we do not address the issue of the use of shorter cost–averaging periods in this investigation.

[12] *See, e.g., Stainless Steel Plate in Coils From Belgium: Final Results of Antidumping Duty Administrative Review*, 73 FR 75398 (December 11, 2008) and accompanying Issues and Decision Memorandum at Comment 4.

Surrogate Country

In the *Preliminary Determination*, we stated that we had selected India as the appropriate surrogate country to use in this investigation for the following reasons: (1) it is a significant producer of comparable merchandise; (2) it is at a similar level of economic development comparable to that of the PRC; and (3) we have reliable data from India that we can use to value the factors of production. *See Preliminary Determination*. For the final determination, we received no comments and made no changes to our findings with respect to the selection of a surrogate country.

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 subject to an investigation in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate. *See 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 *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), and 19 CFR 351.107(d). In the *Preliminary Determination*, we found that Changbao, TPCO and 37 separate rate–applicants demonstrated their eligibility for separate–rate status (collectively, "Separate–Rate Recipients"). For the final determination, we continue to find that the evidence placed on the record of this investigation by TPCO and the remaining Separate Rate Recipients demonstrate both a *de jure* and *de facto* absence of government control, with respect to their respective exports of the merchandise under investigation and, thus, are eligible for separate rate status.

Use of Facts Available

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 subsection 782(d) of the Act, use facts otherwise available in reaching the applicable determination.

Section 782(c)(1) of the Act provides that if an interested party "promptly after receiving a request from {the Department} for information, notifies {the Department} that such party is unable to submit the information requested in the requested form and manner, together with a full explanation and suggested alternative forms in which such party is able to submit the information," the Department may modify the requirements to avoid imposing an unreasonable burden on that party.

Section 782(d) of the Act provides that, if the Department determines that a response to a request for information does not comply with the request, the Department will inform the person submitting the response of the nature of the deficiency and shall, to the extent practicable, provide that person the opportunity to remedy or explain the deficiency. If that person submits further information that continues to be unsatisfactory, or this information is not submitted within the applicable time limits, the Department may, subject to section 782(e), disregard all or part of the original and subsequent responses, as appropriate.

Section 782(e) of the Act states that the Department shall not decline to consider information deemed "deficient" under section 782(d) if: (1) the information is submitted by the established deadline; (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; and (5) the information can be used without undue difficulties.

Furthermore, section 776(b) of the Act states 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 from the administering authority or the Commission, the administering authority or the Commission ..., in reaching the applicable determination under this title, may use an inference that is adverse to the interests of that party in selecting from among the facts otherwise available."[13]

For this final determination, in accordance with sections 773(c)(3)(A)

[13] *See also Statement of Administrative Action ("SAA") accompanying the Uruguay Round Agreements Act (URAA)*, H.R. Rep. No. 103-316, Vol. 1 at 870 (1994).

and (B) of the Act and sections 776(a)(2)(A), (B) and (D) and 776(b) of the Act, we have determined that the use of AFA is warranted for Changbao and the PRC wide entity as discussed below.

Changbao

The Department has determined that the information to construct an accurate and otherwise reliable margin is not available on the record with respect to Changbao because Changbao withheld information that had been requested, significantly impeded this proceeding, and provided information that could not be verified, pursuant to sections 776(a)(1) and (2)(A), (C) and (D) of the of Act.[14] As a result, the Department has determined to apply the facts otherwise available. Further, because the Department finds that Changbao failed to cooperate to the best of its ability, pursuant to section 776(b) of the Act, the Department has determined to use an adverse inference when applying facts available in this review. In addition, we have concluded that the nature of Changbao's unreliable submissions calls into question the reliability of the questionnaire responses in their entirety as submitted by Changbao in this investigation, including Changbao's claim of eligibility for separate rate status. Thus, we find that Changbao is part of the PRC–wide entity for purposes of this investigation.[15]

The PRC Entity (including Changbao)

Because we begin with the presumption that all companies within an NME country are subject to government control and because only the companies listed under the "Final Determination Margins" section below have overcome that presumption, we are applying a single antidumping rate - the PRC–wide rate - to all other exporters of subject merchandise from the PRC, including Changbao.[16] The PRC–wide rate applies to all entries of subject merchandise except for entries from the respondents identified as receiving a separate rate in the "Final Determination Margins" section below.

In the *Preliminary Determination*, the Department found that the PRC–wide entity did not respond to our requests for information because record evidence indicates there were more exporters of OCTG from the PRC during the POI than those that responded to the Quantity & Value questionnaire or the full antidumping questionnaire. Therefore, in the *Preliminary Determination* we treated these PRC producers/exporters as part of the PRC–wide entity because they did not demonstrate that they operate free of government control over their export activities. No additional information was placed on the record with respect to these entities after the *Preliminary Determination*. In addition, because the PRC–wide entity has not provided the Department with the requested information; pursuant to section 776(a)(2)(A) and (C) of the Act, the Department continues to find that the use of facts available is appropriate to determine the PRC–wide rate. Section 776(b) of the Act provides that, in selecting from among the facts otherwise available, the Department may employ an adverse inference if an interested party fails to cooperate by not acting to the best of its ability to comply with requests for information. *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold–Rolled Flat–Rolled Carbon–Quality Steel Products From the Russian Federation*, 65 FR 5510, 5518 (February 4, 2000). *See also, SAA* at 870. We have determined that, because the PRC–wide entity did not respond to our request for information, it has failed to cooperate to the best of its ability. Therefore, the Department finds that, in selecting from among the facts otherwise available, an adverse inference is warranted. As AFA, the Department is applying the rate alleged in the Petition as adjusted by the Department for the initiation.

Partial AFA to TPCO

The Department has also determined that necessary information regarding the downstream sales of TPCO's affiliate, Company B, is not on the record. Further, TPCO failed to report information that had been requested and significantly impeded this proceeding, pursuant to sections 776(a)(1) and (2)(A), and (C) of the of Act, by not reporting certain downstream sales of its affiliate, as requested by the Department.[17] As a result, the Department has determined to apply the facts otherwise available for the unreported downstream sales. Further, because the Department finds that TPCO failed to cooperate to the best of its ability, pursuant to section 776(b) of the Act, the Department has determined to use an adverse inference when applying facts available in this review.[18] As partial AFA, the Department is applying to the unreported sales the rate alleged in the Petition as adjusted by the Department for the initiation.[19]

Corroboration

Section 776(c) of the Act provides that, when the Department relies on secondary information rather than on information obtained in the course of an investigation as facts available, it must, to the extent practicable, corroborate that information from independent sources reasonably at its disposal. Secondary information is described in the *SAA* as "information derived from the petition that gave rise to the investigation or review, the final determination concerning subject merchandise, or any previous review under section 751 concerning the subject merchandise."[20] The *SAA* provides that to "corroborate" means simply that the Department will satisfy itself that the secondary information to be used has probative value.[21] The SAA also states that independent sources used to corroborate may include, for example, published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation.[22] To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information used.[23]

As total AFA the Department preliminarily selected the rate of 99.14 from the Petition.[24] Petitioners' methodology for calculating the export price and normal value ("NV") in the Petition is discussed in the *Initiation Notice*.[25] At the *Preliminary Determination*, in accordance with section 776(c) of the Act, we corroborated our AFA margin by comparing it to the margins we found for the respondents. We found that the margin of 99.14 percent had probative value because it is in the range of

[14] *See* Changbao AFA Memo.

[15] *See* Changbao AFA Memo.

[16] *See, e.g., Synthetic Indigo From the People's Republic of China; Notice of Final Determination of Sales at Less Than Fair Value*, 65 FR 25706 (May 3, 2000).

[17] *See* Issues and Decision Memorandum at Comment 9.

[18] *Id.* at 13-14.

[19] *See* TPCO Final Analysis Memo.

[20] *See SAA* at 870.

[21] *See id.*

[22] *See id.*

[23] *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).

[24] *See Initiation Notice*, 74 FR at 20676.

[25] *See Initiation Notice*, 74 FR at 20674.

margins we found for the mandatory respondents. Accordingly, we found that the rate of 99.14 percent was corroborated within the meaning of section 776(c) of the Act.

Similarly, for the final determination, we have also corroborated our AFA margin by comparing it to the margins we found for the respondents. We find that the margin of 99.14 percent has probative value because it is in the range of margins we found for one of the mandatory respondents. Because no parties commented on the selection of the PRC–wide rate, we continue to find that the margin of 99.14 percent has probative value. Accordingly, we find that the rate of 99.14 percent is corroborated within the meaning of section 776(c) of the Act.

Critical Circumstances

In the *Preliminary Determination*, we found that critical circumstances exist for the PRC–wide entity, however, we did not find that critical circumstances exist with respect to the mandatory respondents or the Separate Rate Recipients. No comments were received regarding the Department's preliminary critical circumstances determination. For the reasons stated in the *Preliminary Determination*, the Department continues to find that critical circumstances do not exist for TPCO or the Separate Rate Recipients.[26] We also continue to find that critical circumstances exist for the PRC entity, and because Changbao is now part of the PRC–wide entity, we also find that critical circumstances exist for Changbao.

Final Determination Margins

We determine that the following percentage weighted–average margins exist for the following entities for the POI:

Exporter	Producer	Weighted–Average Margin Percent
Tianjin Pipe International Economic and Trading Corporation	Tianjin Pipe (Group) Corporation	29.94
Angang Group Hong Kong Co., Ltd.	Angang Steel Co. Ltd.	29.94
Angang Steel Co., Ltd., and Angang Group International Trade Corporation	Angang Steel Co. Ltd.	29.94
Anhui Tianda Oil Pipe Co., Ltd.	Anhui Tianda Oil Pipe Co., Ltd.	29.94
Anshan Zhongyou Tipo Pipe & Tubing Co., Ltd.	Anshan Zhongyou Tipo Pipe & Tubing Co., Ltd.	29.94
Baotou Steel International Economic and Trading Co., Ltd.	Seamless Tube Mill of Inner Mongolia Baotou Steel Union Co., Ltd.[27]	29.94
Benxi Northern Steel Pipes Co., Ltd.	Benxi Northern Steel Pipes Co., Ltd.	29.94
Chengdu Wanghui Petroleum Pipe Co. Ltd.	Chengdu Wanghui Petroleum Pipe Co. Ltd.	29.94
Dalipal Pipe Company	Dalipal Pipe Company	29.94
Faray Petroleum Steel Pipe Co. Ltd.	Faray Petroleum Steel Pipe Co. Ltd.	29.94
Freet Petroleum Equipment Co., Ltd. of Shengli Oil Field, The Thermal Recovery Equipment, Zibo Branch	Freet Petroleum Equipment Co., Ltd. of Shengli Oil Field, The Thermal Recovery Equipment, Zibo Branch	29.94
Hengyang Steel Tube Group International Trading, Inc.	Hengyang Valin MPM Tube Co., Ltd.; Hengyang Valin Steel Tube Co., Ltd.	29.94
Huludao Steel Pipe Industrial Co., Ltd./Huludao City Steel Pipe Industrial Co., Ltd.	Huludao Steel Pipe Industrial Co., Ltd./Huludao City Steel Pipe Industrial Co., Ltd.	29.94
Jiangsu Chengde Steel Tube Share Co., Ltd.	Jiangsu Chengde Steel Tube Share Co., Ltd.	29.94
Jiangyin City Changjiang Steel Pipe Co., Ltd.	Jiangyin City Changjiang Steel Pipe Co., Ltd.	29.94
Pangang Group Beihai Steel Pipe Corporation	Pangang Group Beihai Steel Pipe Corporation	29.94
Pangang Group Chengdu Iron & Steel	Pangang Group Chengdu Iron & Steel	29.94
Qingdao Bonded Logistics Park Products International Trading Co., Ltd.	Shengli Oilfield Highland Petroleum Equipment Co., Ltd.; Shandong Continental Petroleum Equipment Co., Ltd.; Aofei Tele Dongying Import & Export Co., Ltd.; Highgrade Tubular Manufacturing (Tianjin) Co., Ltd.; Cangzhou City Baohai Petroleum Material Co., Ltd.	29.94
Qiqihaer Haoying Iron and Steel Co., Ltd. of Northeast Special Steel Group.	Qiqihaer Haoying Iron and Steel Co., Ltd. of Northeast Special Steel Group	29.94
Shandong Dongbao Steel Pipe Co., Ltd.	Shandong Dongbao Steel Pipe Co., Ltd.	29.94
ShanDong HuaBao Steel Pipe Co., Ltd.	ShanDong HuaBao Steel Pipe Co., Ltd.	29.94
Shandong Molong Petroleum Machinery Co., Ltd.	Shandong Molong Petroleum Machinery Co., Ltd.	29.94
Shanghai Metals & Minerals Import & Export Corp./ Shanghai Minmetals Materials & Products Corp.	Jiangsu Changbao Steel Pipe Co., Ltd.; Huludao Steel Pipe Industrial Co., Ltd.; Northeast Special Steel Group Qiqihaer Haoying Steel and Iron Co., Ltd.; Beijing Youlu Co., Ltd.	29.94
Shanghai Zhongyou Tipo Steel Pipe Co., Ltd.	Shanghai Zhongyou Tipo Steel Pipe Co., Ltd.	29.94
Shengli Oil Field Freet Petroleum Equipment Co., Ltd.	Freet Petroleum Equipment Co., Ltd. of Shengli Oil Field, The Thermal Recovery Equipment, Zibo Branch; Faray Petroleum Steel Pipe Co., Ltd.; Shengli Oil Field Freet Petroleum Steel Pipe Co., Ltd.	29.94
Shengli Oil Field Freet Petroleum Steel Pipe Co., Ltd.	Freet Petroleum Equipment Co., Ltd. of Shengli Oil Field, The Thermal Recovery Equipment, Zibo Branch; Anhui Tianda Oil Pipe Co., Ltd; Wuxi Fastube Dingyuan Precision Steel Pipe Co., Ltd.	29.94

[26] *See Preliminary Determination.*

Exporter	Producer	Weighted–Average Margin Percent
Shengli Oilfield Highland Petroleum Equipment Co., Ltd.	Tianjin Pipe Group Corp.; Goods & Materials Supply Dept. of Shengli Oilfield SinoPEC; Dagang Oilfield Group New Century Machinery Co. Ltd.;Tianjin Seamless Steel Pipe Plant; Baoshan Iron & Steel Co. Ltd	29.94
Shengli Oilfield Shengji Petroleum Equipment Co., Ltd.	Shengli Oilfield Shengji Petroleum Equipment Co., Ltd.	29.94
Tianjin Xingyuda Import and Export Co., Ltd. & Hong Kong Gallant Group Limited	Tianjin Lifengyuanda Steel Group Co., Ltd.	29.94
Tianjin Seamless Steel Pipe Plant	Tianjin Seamless Steel Pipe Plant	29.94
Tianjin Tiangang Special Petroleum Pipe Manufacturer Co., Ltd.	Tianjin Tiangang Special Petroleum Pipe Manufacturer Co., Ltd.	29.94
Wuxi Baoda Petroleum Special Pipe Manufacturing Co., Ltd.	Wuxi Baoda Petroleum Special Pipe Manufacturing Co., Ltd.	29.94
Wuxi Seamless Oil Pipe Co., Ltd.	Wuxi Seamless Oil Pipe Co., Ltd.	29.94
Wuxi Sp. Steel Tube Manufacturing Co., Ltd.	Wuxi Precese Special Steel Co., Ltd.	29.94
Wuxi Zhenda Special Steel Tube Manufacturing Co., Ltd.	Huai'an Zhenda Steel Tube Manufacturing Co., Ltd.	29.94
Xigang Seamless Steel Tube Co., Ltd.	Xigang Seamless Steel Tube Co., Ltd.; Wuxi Seamless Special Pipe Co., Ltd.	29.94
Yangzhou Lontrin Steel Tube Co., Ltd.	Yangzhou Lontrin Steel Tube Co., Ltd.	29.94
Zhejiang Jianli Co., Ltd. & Zhejiang Jianli Steel Tube Co., Ltd.	Zhejiang Jianli Co., Ltd.; Zhejiang Jianli Steel Tube Co., Ltd.	29.94
PRC–wide Entity*		99.14

[27] In the *Preliminary Determination* and the *Amended Preliminary Determination*, we inadvertently identified the producer as Baotou Steel International Economic and Trading Co., Ltd.

*Includes: Jiangsu Changbao Steel Tube Co., Ltd. and Jiangsu Changbao Precision Tube Co., Ltd. and Shengli Oil Field Freet Import & Export Trade Co., Ltd.

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, we are directing CBP to continue to suspend liquidation of all imports of subject merchandise entered or withdrawn from warehouse, for consumption on or after the following dates: (1) for TPCO and the separate rate companies, on or after November 17, 2010, the date of publication of the *Preliminary Determination* in the **Federal Register**, (2) for the PRC–wide entity (except for Changbao), on or after April 19, 2009, which is 90 days prior to the publication of the *Preliminary Determination* (consistent with our finding that critical circumstances exist for the PRC–wide entity), and (3) for Changbao, which is now part of the PRC–wide entity, 90 days prior to the date of publication of this final determination. Because Changbao had a zero margin at the *Preliminary Determination*, we instructed CBP to not suspend liquidation of entries of merchandise exported by Changbao. Accordingly, pursuant to 19 CFR 351.206(a), the Department will first issue suspension of liquidation instructions for Changbao with this final affirmative determination of sales at less than fair value and affirmative finding of critical circumstances. We will instruct CBP to continue to require a cash deposit or the posting of a bond for all companies based on the estimated weighted–average dumping margins shown above.

Additionally, as the Department has determined in its *Certain Oil Country Tubular Goods From the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order*, 75 FR 3203 (January 20, 2010) ("*CVD Final*") that the merchandise under investigation, exported by TPCO, benefitted from an export subsidy, we will instruct CBP to require an antidumping cash deposit or posting of a bond equal to the weighted–average amount by which the NV exceeds the U.S. price for TPCO, as indicated above, minus the amount determined to constitute an export subsidy.[28]

For the two separate–rate companies in this investigation that also participated as mandatory respondents in the CVD investigation (*i.e.*, Wuxi Seamless Oil Pipe Co., Ltd., and Zhejiang Jianli Co., Ltd. & Zhejiang Jianli Steel Tube Co., Ltd.), because it was determined in the *CVD Final* that these companies did not benefit from any export subsidy, we will not make an adjustment to the antidumping duty rate of these companies for purposes of cash deposits.

For the remaining separate–rate companies, we will instruct CBP to adjust the dumping margin by the amount of export subsidies included in the All Other rate from the *CVD Final*.

These suspension of liquidation instructions will remain in effect until further notice.

ITC Notification

In accordance with section 735(d) of the Act, we have notified the International Trade Commission ("ITC") of our final determination of sales at LTFV. As our final determination is affirmative, in accordance with section 735(b)(2) of the Act, within 45 days the ITC will determine whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of the subject merchandise. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all securities posted will be refunded or canceled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess antidumping duties on all imports of the subject merchandise

[28] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Carbazole Violet Pigment 23 From India*, 69 FR 67306, 67307 (November 17, 2004).

entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding APO

This notice also serves as a reminder to the parties subject to administrative protective order ("APO") of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This determination and notice are issued and published in accordance with sections 735(d) and 777(i)(1) of the Act.

Dated: April 8, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

Appendix I

I. General Issues

Comment 1: Labor Wage Rate
Comment 2: Application of Targeted Dumping
Comment 3: Deduction of Domestic Inland Insurance from U.S. Price
Comment 4: Exchange Rate Rupees to U.S. Dollars
Comment 5: Deduction of Chinese VAT from U.S. Price
Comment 6: Zeroing
Comment 7: Double Counting

II. TPCO Specific Issues

Comment 8: Total AFA to TPCO
Comment 9: Partial AFA for certain TPCO Transactions
Comment 10: TPCO Affiliations

III. Credit Expense

Comment 11: Credit Expense

IV. U.S. Price Deductions

Comment 12: Certain Deduction from U.S. Price

V. Surrogate Financial Statements

Comment 13: Financial Statements for Surrogate Ratios

VI. Transportation Costs

Comment 14: Water Transportation Costs
Comment 15: Addition of Freight Costs to ME Purchases

VII. Certain Conversion Factor Issues

Comment 16: Conversion Factors for Argon, Nitrogen and Oxygen

VIII. By–Product Offsets

Comment 17: By–product Offset for Steel Scrap

IX. General Surrogate Value Issues

Comment 18: Value of Ancillary Materials
Comment 19: Value of FOPs Purchased through Distributor
Comment 20: Value for Billet
Comment 21: Value for Coal
Comment 22: Value for Compressed Air
Comment 23: Value for Scrap Input
Comment 24: Value for Iron Ore Pellets
Comment 25: Value of Natural Gas
Comment 26: Value of Micro and Mid–Chromium
Comment 27: Value of Iron Ore and Iron Powder
Comment 28: Values of Oxygen and Nitrogen
Comment 29: Value of Pig Iron

X. Changbao Related Issues

Comment 30: Total AFA to Changbao
Comment 31: Changbao's Sales to Unaffiliated PRC Trading Companies

[FR Doc. 2010–8994 Filed 4–16–10; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–805]

Certain Circular Welded Non-Alloy Steel Pipe From Mexico: Final Results of Antidumping Duty Administrative Review and Rescission of Administrative Review in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 7, 2009, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on certain circular welded non-alloy steel pipe from Mexico. *See Certain Circular Welded Non-Alloy Steel Pipe From Mexico; Preliminary Results of Antidumping Duty Administrative Review,* 74 FR 64049 (December 7, 2009) (*Preliminary Results*). While the review originally covered eight companies, we rescinded the review with respect to all but the remaining three respondents. *See Certain Circular Welded Non-Alloy Steel Pipe from Mexico: Notice of Partial Rescission of Antidumping Duty Administrative Review,* 74 FR 20919 (May 6, 2009). We therefore treated Tuberia Nacional, S.A. de C.V. (TUNA), Ternium Mexico, S.A. de C.V. (Ternium) [1] and Mueller Comercial de Mexico, S. de R.L. (Mueller) as mandatory respondents for the period November 1, 2007, to October 31, 2008. Based on our analysis of the comments received, we have made no changes from the *Preliminary Results.* We have listed the final dumping margin below in the section entitled "Final Results of Review."

DATES: *Effective Date:* April 19, 2010.

FOR FURTHER INFORMATION CONTACT: Maryanne Burke 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) 482–5604 and (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2009, the Department published in the **Federal Register** the preliminary results of the administrative review of the antidumping duty order on certain circular welded non-alloy steel pipe from Mexico for the period November 1, 2007, to October 31, 2008. *See Preliminary Results.* In response to the Department's invitation to comment on the preliminary results of this review, petitioner United States Steel Corporation (U.S. Steel), and respondents Mueller and Ternium filed their case briefs on January 6, 2010. U.S. Steel and respondent TUNA submitted rebuttal briefs on January 14, 2010.[2]

As explained in the memorandum from the Deputy Assistant Secretary for Import Administration, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from February 5, through February 12, 2010. Thus, all deadlines in this segment of the proceeding have been extended by seven days. The revised deadline for the final results of this administrative review is now April 13, 2010. *See* Memorandum to the Record from Ronald Lorentzen, DAS for Import Administration, regarding "Tolling of Administrative Deadlines As a Result of the Government Closure During the

[1] Consistent with the *Preliminary Results,* and the Department's changed circumstances review of this order which found Ternium the successor-in-interest to Hylsa, we continue to consider Ternium and Hylsa as a single entity. *See Preliminary Results; see also Final Results of Antidumping Duty Changed Circumstances Review: Certain Circular Welded Non-Alloy Steel Pipe and Tube from Mexico,* 74 FR 41681 (August 18, 2009).

[2] On January 7, 2010, U.S. Steel requested an extension of its rebuttal brief which was granted by the Department. The new deadline for all parties' rebuttal briefs was set for January 14, 2010.

Recent Snowstorm," dated February 12, 2010.

Scope of the Order

The products covered by this order are circular welded non-alloy steel pipes and tubes, of circular cross-section, not more than 406.4 millimeters (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, beveled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipes and tubes and are intended for the low pressure conveyance of water, steam, natural gas, and other liquids and gases in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses, and generally meet ASTM A–53 specifications. Standard pipe may also be used for light load-bearing applications, such as for fence tubing, and as structural pipe tubing used for framing and support members for reconstruction or load-bearing purposes in the construction, shipbuilding, trucking, farm equipment, and related industries. Unfinished conduit pipe is also included in these orders. All carbon steel pipes and tubes within the physical description outlined above are included within the scope of this order, except line pipe, oil country tubular goods, boiler tubing, mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished conduit. Standard pipe that is dual or triple certified/stenciled that enters the U.S. as line pipe of a kind used for oil or gas pipelines is also not included in this order.

The merchandise covered by the order and subject to this review are currently classified in the *Harmonized Tariff Schedule of the United States* (HTSUS) at subheadings: 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90. Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of these proceedings is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by interested parties in this administrative review are addressed in the Issues and Decision Memorandum (Decision Memorandum) from John M. Andersen, Acting Deputy Assistant Secretary for Import Administration, to Ronald K. Lorentzen, Deputy Assistant Secretary for Import Administration, dated April 13, 2010, which is hereby adopted by this notice. A list of the issues which parties have raised and to which we have responded, all of which are in the Decision Memorandum, is attached to this notice as an appendix. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum, which is on file in the Central Records Unit in room 1117 of the main Department building. In addition, a complete version of the Decision Memorandum can be accessed directly via the Internet at *http://ia.ita.doc.gov/frn/index.html.* The paper copy and electronic version of the Decision Memorandum are identical in content.

Rescission of Review in Part

In the *Preliminary Results,* we preliminarily found TUNA's claim that it made no shipments of subject merchandise during the period of review was consistent with import data provided by U.S. Customs and Border Protection (CBP) as well as additional information developed on the record of this review. Accordingly, we stated our intent to rescind the administrative review with respect to this company. *See Preliminary Results.* We received comments about this issue from TUNA and U.S. Steel, and continue to find that TUNA did not make entries, exports, or sales of subject merchandise during the POR. For the final results of this review, we are, therefore, rescinding the review with respect to TUNA.

Use of Total Adverse Facts Available

The Department found in the *Preliminary Results* that Ternium and Mueller failed to cooperate to the best of their ability by withholding information requested by the Department's questionnaire, and thereby impeded the Department's proceeding. *See Preliminary Results.* Therefore, in accordance with section 776(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.308(c), the Department preliminarily selected 48.33 percent as the adverse facts available dumping margin. The Department received comments regarding its preliminary application of the adverse facts available dumping margin to Ternium and Mueller. For these final results, the Department has not altered its analysis or decision to apply the adverse facts available dumping margin to Ternium and Mueller. *See* accompanying Decision Memorandum for the issues raised by the parties and addressed by the Department.

Final Results of Review

We determine the following percentage margin exists for the period November 1, 2007 to October 31, 2008:

Manufacturer/ Exporter	Weighted-Average margin (percentage)
Ternium	48.33
Mueller	48.33

Assessment

The Department will determine, and CBP shall assess, antidumping duties on all appropriate entries, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.212(b). We will issue appraisement instructions directly to CBP to assess antidumping duties on appropriate entries by applying the assessment rate to the entered value of the merchandise. Pursuant to 19 CFR 356.8(a), the Department intends to issue assessment instructions to CBP 41 days after the date of publication of these final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of these final results for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results of administrative review, consistent with section 751(a)(1) of the Act: (1) The cash deposit rate for the reviewed companies will be the rate listed above; (2) if the exporter is not a firm covered in this review, but was covered in a previous review or the original less-than-fair-value (LTFV) investigation, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV 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; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 32.62 percent, the all-others rate established in the LTFV investigation. *See Final Determination of Sales at Less Than Fair Value: Circular Welded Non-Alloy Steel Pipe From Mexico,* 57 FR 42953 (September 17, 1992). These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

This notice also serves as a final 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 Department's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 13, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

Appendix—List of Issues in Decision Memorandum

Comment 1: Application of Total AFA to Ternium
Comment 2: Application of Total AFA to Mueller
Comment 3: Rescission of Administrative Review for TUNA

[FR Doc. 2010–8991 Filed 4–16–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XV88

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The North Pacific Fishery Management Council's Gulf of Alaska (GOA) and Bering Sea/Aleutian Islands (BSAI) groundfish plan teams will meet via teleconference May 6, 2010, 12:30 p.m. Alaska Standard Time (AST) to review proposals for models to be considered for inclusion in the GOA and BSAI Pacific cod assessments.

DATES: The teleconference will be held on May 6, 2010; telephone: (907) 271–2896.

ADDRESSES: Listening sites - North Pacific Fishery Management Council, 605 W 4th Avenue, Anchorage, AK; and Alaska Fisheries Science Center, 7600 Sand Point Way N.E., Building 4, Seattle, WA.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Jane DiCosimo; North Pacific Fishery Management Council; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: Agenda: Review proposals for models Pacific cod stock assessments. The agenda is posted on the Council website at: *http://www.alaskafisheries.noaa.gov/npfmc/*

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, (907) 271–2809, at least 5 working days prior to the meeting date.

Dated: April 14, 2010.

Tracey L. Thompson,

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

[FR Doc. 2010–8898 Filed 4–16–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XV64

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Rocket Launches from Kodiak, AK

AGENCY: National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice; Issuance of a Letter of Authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) and implementing regulations, notification is hereby given that a Letter of Authorization (LOA) has been issued to the Alaska Aerospace Corporation (AAC, formerly known as the Alaska Aerospace Development Corporation), to take Steller sea lions (*Eumetopias jubatus*) and Pacific harbor seals (*Phoca vitulina richardsi*) incidental to rocket launches from the Kodiak Launch Complex (KLC).

DATES: Effective April 15, 2010, through February 28, 2011.

ADDRESSES: The LOA and supporting documentation are available by writing to Michael Payne, Chief, Permits, Conservation, and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225, by telephoning one of the contacts listed here (see **FOR FURTHER INFORMATION CONTACT**), or online at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm*. Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Howard Goldstein or Jaclyn Daly, Office of Protected Resources, NMFS, (301) 713–2289, or Brad Smith, Alaska Regional Office, NMFS, (907) 271–3023.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1361 *et seq.*) directs the National Marine Fisheries Service (NMFS) to allow, on request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and regulations are issued. Under the MMPA, the term "taking" means to harass, hunt, capture, or kill or to attempt to harass, hunt, capture or kill marine mammals.

Authorization may be granted for periods up to five years if NMFS finds, after notification and opportunity for public comment, that the taking will have a negligible impact on the species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses. In addition, NMFS must prescribe regulations that include permissible methods of taking and other means effecting the least practicable adverse impact on the species and its habitat and on the availability of the species for subsistence uses, paying particular attention to rookeries, mating grounds, and areas of similar significance. The regulations must include requirements for monitoring and reporting of such taking.

Regulations governing the taking of Steller sea lions and harbor seals, by harassment, incidental to rocket launches at KLC, became effective on February 27, 2006 (71 FR 4297), and remain in effect until February 28, 2011. For detailed information on this action, please refer to that document. These regulations include mitigation, monitoring, and reporting requirements for the incidental taking of marine mammals during rocket launches at KLC.

Summary of Request

NMFS received a request for an LOA pursuant to the aforementioned regulations that would authorize, for a period not to exceed 1 year, take of marine mammals incidental to rocket launches at KLC.

Summary of Activity and Monitoring Under the Current LOA

No launch operations were conducted at KLC in 2009, and none were predicted or scheduled prior to expiration of the current LOA. As such, the most recent reports concerning activity and monitoring at KLC were submitted in compliance with the 2008 LOA. A summary of those reports (R&M Consultants, 2008) follows.

FTX–03 Mission

Two launches were conducted at KLC between March 12, 2008, and March 11, 2009. The first was a monitored launch of a Flight Test Experimental–03 (FTX–03) long range ballistic missile on July 18, 2008 at 1:47:00 a.m. ADT. Aerial surveys to document marine mammals in the primary survey area (6–mile radius of the KLC launch pads) were flown using single-engine fixed-wing aircraft 1 day prior to (July 17), the day of (July 18), and 3 days (July 19–21) post launch. On July 17, 2008, video equipment and a noise monitor were deployed on the northeast side of Ugak Island, 4.2 miles (6.8 km) from the launch site, and another noise monitor was deployed on Narrow Cape , 0.9 miles (1.4 km) from the launch site. Sound level monitoring equipment at Ugak Island registered noise above general ambient levels for one minute thirty three seconds with an SEL of 89.6 dBA. The one-second broadband peak noise level was 108.3 dBC. The 1/3 octave broadband noise level peaked between 63 and 250 Hz with a maximum noise level of 90.7 dB at 100 Hz. Sound level monitoring equipment at Narrow Cape registered noise above general ambient levels for one minute fifty seconds with an SEL of 112.6 dBA. The one-second broadband peak noise level was 145.6 dBC. The 1/3 octave broadband noise level peaked between 63 and 400 Hz with a maximum noise level at 105.8 dB at 315 Hz.

Video equipment was focused on the Steller sea lion haulout on the east side of Ugak Island because no seal lions were present at the traditional haulout on the gravel spit at Ugak. This haulout was occupied by 1–5 seal lions during the aerial surveys, and 0–3 sea lions during video monitoring. However, the camera battery was depleted about two hours before the launch so the immediate effects of the launch on Steller sea lions could not be determined. However, three sea lions were seen at the haulout during the aerial survey conducted within two hours after the launch, the same number recorded when the camera battery died; therefore, if any behavioral impacts did occur, they were short lived.

Harbor seals were the most abundant marine mammal counted. Daily totals ranged from 610 seals on July 20, 2008 to 1,534 seals on July 21, 2008. The count of harbor seals before the launch (853 seals) was similar immediately post launch (840 seals). For the three days after launch, 744, 610, and 1,534 harbor seals, respectively, were sighted in the primary study area. Therefore, NMFS does not expect that the launch had a long term impact on harbor seals in the action area.

FTG–05 Mission

The second monitored launch of an Flight Test Ground-based Interceptor–05 (FTG–05) ballistic missile was conducted at KLC on December 5, 2008 at 11:04 a.m. ADT. Five monitoring surveys were scheduled between December 4–8, 2008; however, foul weather precluded flying from all but one day. No monitoring survey was completed pre-launch and only one survey was completed post-launch; however, one aerial survey was flown over part of the primary study area three days before the launch (December 2) prior to the designated monitoring surveys. Foul weather precluded helicopter access to Ugak Island, therefore no video equipment or sound monitoring device was deployed at this location. However, a sound level monitor was deployed on Narrow Cape. This noise monitoring device registered noise above general ambient levels for one minute forty one seconds with an SEL of 112.4 dBA. The one-second broadband peak noise level was 126.1 dBC. The 1/3 octave broadband noise level peaked between 63 and 400 Hz with a maximum noise level at 106.6 dB at 200 Hz.

Steller sea lions did not use the spit on northern Ugak Island (the traditional haulout site) during the December 7 survey; however, this has been the trend during the past few years. One sea lion was sighted during that day on the suprtidal rock on the eastern side of Ugak, the same location where they were sighted during the FTX–03 launch, as described above.

During the December 7 survey, 971 harbor seals were sighted in the primary study area. All were sighted on Ugak Island with the largest single haulout located on the northeast side of the island with 444 seals. Because only one survey was completed and no video monitoring system was set up during the FTG–05 launch, the actual impacts to Steller sea lions and harbor seals can not be determined. However, AAC did collect video monitoring data of Steller sea lions during a FTG–02 launch in 2006. During that launch, two sea lions were present on Ugak Rock. The animals raised their heads in response to launch noise, which peaked at 105.6 dBC and had an SEL of 90.1dBA over one minute and eight seconds; however, they did not flush into the water. For comparative purposes, the Narrow Cape the peak noise level during this launch was 128 dBC with a SEL of 112.5dBA over one minute 23–seconds which is comparable to the December FTG–05 launch, as described above. Therefore, NMFS anticipates that reactions of Steller sea lions, if present, were likely similar to those recorded previously.

In summary, NMFS concludes the impacts from the FTX–03 and FTG–05 flight were similar based on similar acoustic monitoring measurements from both launches. No mortality or injury was observed during the FTX–03 launch and likely did not occur during the FTG–05 launch. As described in reporting from the 2008 LOA, the applicant conducted activities as described in the rule, implemented mitigation measures as stipulated in the LOA, and conducted monitoring required under the LOA. Monitoring reports indicated that take of marine mammals did not exceed numbers or level authorized by the LOA and analyzed in the associated rule. During the period of the current LOA, the applicant has not conducted any launch activities, and none are scheduled prior to expiration of the current LOA. As such, the applicant has conformed to the stipulations of the LOA. Based on these actions, the findings of negligible impact, no unmitigable adverse impact, and take of only small numbers are still applicable.

Authorization

Accordingly, NMFS has issued an LOA to AAC authorizing takes of marine mammals incidental to rocket launches

at the KLC. Issuance of this LOA is based on findings, described in the preamble to the final rule (71 FR 4297, January 26, 2006) and supported by information contained in AAC's required 2008 annual report (no launch activities took place in 2009), that the activities described under this LOA will result in the take of small numbers of marine mammals, have a negligible impact on marine mammal stocks, and will not have an unmitigable adverse impact on the availability of the affected marine mammal stocks for subsistence uses.

Dated: April 12, 2010.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2010–8974 Filed 4–19–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Acting Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before June 18, 2010.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: April 13, 2010.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management.

Office of Planning, Evaluation and Policy Development

Type of Review: New.

Title: Study of School Turnaround (Case Studies of Schools Receiving School Improvement Grant Funds).

Frequency: Annually.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 1,267.

Burden Hours: 4,206.

Abstract: The study is designed to document over time the intervention models, approaches, and strategies adopted and implemented by a subset of schools receiving federal School Improvement Grant funds. Data collection includes interviews with state, local district and school officials, parents and students, collection of school-level fiscal data, and observations in 50 school sites receiving School Improvement Grants (SIGs) authorized under Title I, Section 1003(G). The data collected through the survey will inform the documentation, over time, of the intervention models, approaches and strategies adopted and implemented by a subset of schools receiving SIG funds.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4276. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2010–8809 Filed 4–16–10; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Privacy Act of 1974; System of Records

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice of an altered system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), 5 United States Code (U.S.C.) 552a, the Chief Operating Officer for Federal Student Aid (FSA) of the U.S. Department of Education (the Department) publishes this notice proposing to revise the system of records entitled "Student Aid Internet Gateway (SAIG), Participation Management System" (18–11–10).

The SAIG, Participation Management System is a system of records containing contact information that individuals affiliated with an authorized entity provide to request electronic access to the Department's Title IV Federal Student Aid Systems. This notice updates the categories of individuals covered by this system to include individuals affiliated with secondary schools, local educational agencies (LEAs) and States who are authorized by the Department and their respective secondary school, LEA or State to access the Department's Title IV Federal Student Aid Systems.

This change to the SAIG, Participation Management System is needed to enable the Department to implement a program designed to improve access and promote enrollment in postsecondary education by facilitating students' completion of the Free Application for Federal Student Aid (FAFSA). As part of this program (the FAFSA Completion program), the Department will authorize a small number of secondary schools and LEAs to enroll through the SAIG,

Participation Management System to enable these entities to use the Department's Title IV Federal Student Aid Systems to obtain information about their students' completion of the FAFSA. In future years, the Department may seek to expand the FAFSA Completion program to other secondary schools, LEAs, and States across the Nation, which would substantially expand the number of secondary schools, LEAs and States approved by the Department to access the Department's Title IV Federal Student Aid Systems to determine whether their students have completed the FAFSA.

While the FAFSA Completion program provided the initial impetus for the Department to update the SAIG, Participation Management System, the Department has also determined that other changes are appropriate. Specifically, through this notice, the Department proposes to update the system locations, the categories of records maintained in this system, the system's purposes, and the system's routine uses (by, for example, adding an additional routine use, as required by the Office of Management and Budget (OMB)).

DATES: We must receive your comments about this proposed system of records on or before May 19, 2010.

The Department filed a report describing the altered system of records covered by this notice with the Chair of the Senate Committee on Homeland Security and Governmental Affairs, the Chair of the House Committee on Oversight and Government Reform, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on April 14, 2010. This altered system of records will become effective at the later date of: (1) The expiration of the 40-day period for OMB review on May 24, 2010; or (2) the expiration of a 30-day OMB Review period on May 19, 2010, if OMB grants the Department's request for a 10-day waiver of the review period, unless the system of records needs to be changed as a result of public comment or OMB review.

ADDRESSES: Address all comments about the proposed altered system of records to Director, Application Processing Division, Program Management Systems, 830 First Street, NE., room 63C4, Union Center Plaza (UCP), Washington, DC 20202–5454. If you prefer to send your comments through the Internet, use the following address: *comments@ed.gov*.

You must include the term "Student Aid Internet Gateway, Participation Management System" in the subject line of your electronic message.

During and after the comment period, you may inspect all public comments about this notice in room 44D2, UCP, 4th Floor, 830 First Street, NE., Washington, DC, between the hours of 8 a.m. and 4:30 p.m., local time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Director, Application Processing Division, Program Management Systems, 830 First Street, NE., room 63C4, UCP, Washington, DC 20202–5454. *Telephone number:* (202) 377–3205. 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 accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

SUPPLEMENTARY INFORMATION:

Preamble

The Privacy Act (5 U.S.C. 552a(e)(4)) requires the Department to publish in the **Federal Register** this notice of an altered system of records maintained by the Department. The Department's regulations implementing the Privacy Act are contained in the Code of Federal Regulations (CFR) in 34 CFR part 5b.

The Privacy Act applies to a record about an individual that is maintained in a system of records from which information is retrieved by a unique identifier associated with each individual, such as a name or Social Security number. The information about each individual is called a "record," and the system, whether manual or computer-based, is called a "system of records."

The Privacy Act requires each agency to publish notices of altered systems of records in the **Federal Register** and to prepare, whenever the agency publishes a new system of records or makes a significant change to an established system of records, reports to the Chair of House Committee on Oversight and Government Reform of the House of Representatives, and the Chair of the Committee on Homeland Security and Governmental Affairs of the Senate, and the Administrator of the Office of Information and Regulatory Affairs, OMB.

A system of records is considered "altered" whenever an agency expands the types or categories of information maintained, significantly expands the types or categories of individuals about whom records are maintained, changes the purpose for which the information is used, changes the equipment configuration in a way that creates substantially greater access to the records, or adds a routine use disclosure to the system. Since the last correction to this system of records, which was published in the **Federal Register** on January 28, 2005 (70 FR 4112–4115), a number of changes are needed to update the current system of records. Most significantly, this notice updates the categories of individuals covered by this system to include individuals affiliated with secondary schools, LEAs and States who are authorized by the Department and their respective secondary school, LEA or State to access the Department's Title IV Federal Student Aid Systems. This notice also updates the system locations, the categories of records maintained in the system, the system's purposes, adds an additional routine use disclosure that is required by OMB, and makes other minor updates to the system.

Electronic Access to This Document

You may view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister/index.html*.

To use PDF you must have the Adobe Acrobat Reader, which is available free at this site.

Note: The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html*.

Dated: April 14, 2010.

William J. Taggart,

Chief Operating Officer, Federal Student Aid U.S. Department of Education.

For the reasons discussed in the preamble, the Chief Operating Officer, Federal Student Aid of the U.S.

Department of Education (Department) publishes a notice of an altered system of records to read as follows:

System Number:

18–11–10.

SYSTEM NAME:

Student Aid Internet Gateway (SAIG), Participation Management System.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Pearson, PLC, 2510 N. Dodge, Iowa City IA 52245–0030. (This facility hosts the database for the Participation Management System.)

Vangent, Inc., 2450 Oakdale Boulevard, Coralville IA 52241–9728. (This facility stores paper documents that are held for less than 12 months.)

Iron Mountain, 4437 121st Street, Urbandale, IA 50323–2313. (This facility stores paper documents for documents that are held for more than 12 months.)

Virtual Data Center (VDC), Dell Perot System, 2300 West Plano Parkway, Plano, TX 75075–8427. (This facility hosts the SAIG Enrollment Web site (titled FSAWebEnrollment.ed.gov) through which users enroll for electronic access to the Department's Title IV Federal Student Aid Systems.)

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system contains records on those individuals who are eligible to participate in the Department's Title IV Federal Student Aid Systems—to participate in the electronic exchange of data with the Department of Education via the SAIG, or enroll in the Participation Management System for access to the Department's Central Processing System (CPS) Online, eCampus-Based (eCB) System, National Student Loan Data System (NSLDS) Online, Common Origination and Disbursement (COD) System, Financial Management System (FMS), Debt Management and Collections System (DMCS), Title IV Additional Servicers (TIVAS), and Access Information Management System (AIMS). Those individuals eligible to participate include: student financial aid administrators, authorized employees or representatives of postsecondary institutions, authorized employees or representatives of third-party servicers, authorized employees or representatives of lenders, authorized employees or representatives of guaranty agencies, authorized employees or representatives of State scholarship programs, authorized employees or representatives of States, authorized employees or representatives of LEAs, and authorized employees or representatives of secondary schools.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of contact information that individuals affiliated with an authorized entity (i.e., postsecondary institutions, third party servicers, lenders, guaranty agencies, State scholarship programs, States, LEAs and secondary schools that the Department authorizes to access the Department's Title IV Federal Student Aid Systems) provide to request electronic access to the Department's Title IV Federal Student Aid Systems. This contact information includes the individual's name, address, and other authentication information (mother's maiden name, user's Social Security number, and the user's date of birth).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title IV of the Higher Education Act of 1965, as amended (HEA); 20 U.S.C. 1070 *et seq.* The collection of Social Security numbers of users of this system is authorized by 31 U.S.C. 7701 and Executive Order 9397, as amended by Executive Order 13478 (November 18, 2008).

PURPOSE(S):

The information in this system is maintained for the purposes of: (1) Processing stored data from the SAIG Enrollment Forms (Web and paper versions); (2) maintaining the SAIG Enrollment Web site (titled FSAWebEnrollment.ed.gov); (3) managing the assignment of individual electronic SAIG mailbox numbers, known as "TG numbers"; and (4) authenticating users of the CPS Online, eCB System, NSLDS Online, COD System, FMS, DMCS, TIVAS, and AIMS.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The Department may disclose information contained in a record in this system of records under the routine uses listed in this system of records without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected. These disclosures may be made on a case-by-case basis or, if the Department has complied with the computer matching requirements of the Privacy Act of 1974, as amended (Privacy Act), under a computer matching agreement.

(1) *Program Disclosures.* The Department may disclose records maintained in the SAIG, Participation Management System for the purpose of allowing authorized users who are eligible to participate in the electronic exchange of data with the Department to transmit files to and from the following Department databases and access the Department's Web sites online, based on the approved program functions of each of the Department's systems that include, but are not limited to the following:

(a) COD System;

(b) CPS, under the Federal Student Aid Application File;

(c) eCB System;

(d) NSLDS;

(e) FMS;

(f) DMCS, under Common Services for Borrowers (CSB);

(g) TIVAS; and

(h) AIMS.

(2) *Freedom of Information Act (FOIA) or Privacy Act Advice Disclosure.* The Department may disclose records to the Department of Justice (DOJ) or the Office of Management and Budget (OMB) if the Department seeks advice regarding whether records maintained in this system of records are required to be disclosed under the FOIA or the Privacy Act.

(3) *Disclosure to the DOJ.* The Department may disclose records to the DOJ to the extent necessary for obtaining DOJ advice on any matter relevant to an audit, inspection, or other inquiry related to the programs covered by this system.

(4) *Contract Disclosure.* If the Department contracts with an entity to perform any function that requires disclosing records to the contractor's employees, the Department may disclose the records to those employees. Before entering into such a contract, the Department shall require the contractor to establish and maintain the safeguards required under the Privacy Act (5 U.S.C. 552a(m)) with respect to the records in the system.

(5) *Litigation and Alternative Dispute Resolution (ADR) Disclosures.*

(a) *Introduction.* In the event that one of the following parties is involved in litigation or ADR, or has an interest in litigation or ADR, the Department may disclose certain records to the parties described in paragraphs (b), (c), and (d) of this routine use under the conditions specified in those paragraphs:

(i) The Department, or any of its components;

(ii) Any Department employee in his or her official capacity;

(iii) Any Department employee in his or her individual capacity where the DOJ agrees to or has been requested to provide or arrange for representation of the employee;

(iv) Any Department employee in his or her individual capacity where the Department has agreed to represent the employee;

(v) The United States where the Department determines that the litigation is likely to affect the Department or any of its components.

(b) *Disclosure to DOJ.* If the Department determines that disclosure of certain records to the DOJ is relevant and necessary to litigation or ADR, and is compatible with the purpose for which the records were collected, the Department may disclose those records as a routine use to the DOJ.

(c) *Adjudicative Disclosures.* If the Department determines that disclosure of certain records to an adjudicative body before which the Department is authorized to appear or to an individual or entity designated by the Department or otherwise empowered to resolve or mediate disputes, is relevant and necessary to the litigation or ADR, the Department may disclose those records as a routine use to the adjudicative body, individual, or entity.

(d) *Parties, Counsel, Representatives and Witnesses.* If the Department determines that disclosure of certain records to a party, counsel, representative or witness is relevant and necessary to the litigation or ADR, the Department may disclose those records as a routine use to the party, counsel, representative or witness.

(6) *Research Disclosure.* The Department may disclose records to a researcher if an appropriate official of the Department determines that the individual or organization to which the disclosure would be made is qualified to carry out specific research related to functions or purposes of this system of records. The official may disclose records from this system of records to that researcher solely for the purpose of carrying out that research related to the functions or purposes of this system of records. The researcher shall be required to maintain Privacy Act safeguards with respect to the disclosed records.

(7) *Congressional Member Disclosure.* The Department may disclose records to a Member of Congress in response to an inquiry from the Member made at the written request of the individual whose records are being disclosed. The Member's right to the information is no greater than the right of the individual who requested it.

(8) *Disclosure for Use by Other Law Enforcement Agencies.* The Department may disclose information to any Federal, State, or local authority responsible for enforcing, investigating, or prosecuting violations of administrative, civil, or criminal law or regulation if that information is relevant to any enforcement, regulatory, investigative, or prosecutorial responsibility within the receiving entity's jurisdiction.

(9) *Enforcement Disclosure.* In the event that information in this system of records indicates, either on its face or in connection with other information, a violation or potential violation of any applicable statute, regulation, or order of a competent authority, the Department may disclose the relevant records to the appropriate agency, whether foreign, Federal, State, tribal or local, charged with the responsibility of investigating or prosecuting that violation or charged with enforcing or implementing the statute, Executive Order, rule, regulation, or order issued pursuant thereto.

(10) *Employment, Benefit, and Contracting Disclosure.*

(a) *For Decisions by the Department.* The Department may disclose a record to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement or other pertinent records, or to another public authority or professional organization, if necessary to obtain information relevant to a Department decision concerning the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

(b) *For Decisions by Other Public Agencies and Professional Organizations.* The Department may disclose a record to a Federal, State, local, or foreign agency or other public authority or professional organization, in connection with the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit, to the extent that the record is relevant and necessary to the receiving entity's decision on the matter.

(11) *Employee Grievance, Complaint or Conduct Disclosure.* If a record is relevant and necessary to an employee grievance, complaint, or disciplinary action, the Department may disclose a record in this system of records to another agency of the Federal Government if the record is relevant to one of the following proceedings regarding a present or former employee of the Department: Complaint, grievance, discipline or competence determination proceedings. The disclosure may only be made during the course of the proceeding.

(12) *Labor Organization Disclosure.* The Department may disclose records from this system of records to an arbitrator to resolve disputes under a negotiated grievance process or to officials of a labor organization recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation.

(13) *Disclosure in the Course of Responding to a Breach of Data.* The Department may disclose records from this system to appropriate agencies, entities, and persons when (a) the Department suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the Department has determined that as a result for the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure pursuant to 5 U.S.C. 552a(b)(12): The Department may disclose the following information to a consumer-reporting agency regarding a valid overdue claim of the Department: (1) The name, address, taxpayer identification number and other information necessary to establish the identity of the individual responsible for the claim; (2) the amount, status, and history of the claim; and (3) the program under which the claim arose. The Department may disclose the information specified in this paragraph under 5 U.S.C. 552a(b)(12) and the procedures contained in 31 U.S.C. 3711(f). A consumer reporting agency to which these disclosures may be made is defined at 15 U.S.C. 1681a(f) and 31 U.S.C. 3701(a)(3).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in a computer database as well as in hard copy. All hard copy forms are loaded into an imaging system accessible through internal systems only. Paper documents less than 12-months old are stored in locked file cabinets at the Vangent, Inc.

facility in Coralville, Iowa. Paper documents older than 12 months are stored at Iron Mountain secure storage facility. Documents are stored for three years after final contract payment. After the three-year period, documents are subsequently sent to the Federal Records Center for storage.

RETRIEVABILITY:

All individuals affiliated with authorized entities that have been granted access ("users of the SAIG, Participant Management System") to the Department's Title IV Federal Student Aid Systems whose information is included in this system of records have a unique user identification (ID) with a password. Records are retrieved by the names of the individual user and/or their unique system User ID.

SAFEGUARDS:

All users of the SAIG, Participation Management System will have a unique user ID with a password.

All physical access to the data housed at the Pearson location and within the VDC, and the locations of Department contractors where this system of records is maintained, is controlled and monitored by security personnel who check each individual entering the building for his or her employee or visitor badge.

The computer system employed by the Department offers a high degree of resistance to tampering and circumvention. This security system limits data access to Department and contract staff on a "need-to-know" basis, and controls individual users' ability to access and alter records within the system.

All interactions by users of the SAIG, Participation Management System are recorded.

RETENTION AND DISPOSAL:

Documents are stored for 3 years after a user of the SAIG, Participation Management System's individual enrollment account is terminated or closed. Thereafter, documents are sent to the Federal Records Center for storage. These records are covered by the General Records Schedule (GRS) 24, Item 6(a). The retention requirement is to destroy/delete the record 6 years after the user account is terminated or password is altered, or when no longer needed for investigative or security purposes, whichever is later.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Application Processing Division, Program Management Systems, 830 First Street, NE., room 63C4, Union Center Plaza (UCP), Washington, DC 20202–5454.

NOTIFICATION PROCEDURE:

If you wish to determine whether a record exists regarding you in this system of records, you must provide the system manager your name, date of birth, and Social Security number. Requests for notification about whether the system of records contains information about an individual must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

RECORD ACCESS PROCEDURES:

If you wish to gain access to a record in this system, you must contact the system manager and provide information as described in the Notification Procedures. Such requests must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

CONTESTING RECORD PROCEDURES:

If you wish to contest or change the content of a record about you in the system of records, you must contact the system manager with the information described in the notification procedures. Requests to amend a record must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.7.

RECORD SOURCE CATEGORIES:

Information in this system is obtained from the following entities: student financial aid administrators, postsecondary institutions, third-party servicers, lenders, guaranty agencies, State scholarship programs, States, LEAs, and secondary schools.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2010–8959 Filed 4–16–10; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9139–2]

Announcement of the Board of Trustees for the National Environmental Education Foundation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The National Environmental Education Foundation was created by Section 10 of Public Law 101–619, the National Environmental Education Act of 1990. It is a private 501(c)(3) non-profit organization established to promote and support education and training as necessary tools to further environmental protection and sustainable, environmentally sound development. It provides the common ground upon which leaders from business and industry, all levels of government, public interest groups, and others can work cooperatively to expand the reach of environmental education and training programs beyond the traditional classroom. The Foundation supports a grant program that promotes innovative environmental education and training programs; it also develops partnerships with government and other organizations to administer projects that promote the development of an environmentally literate public. The Administrator of the U.S. Environmental Protection Agency, as required, by the terms of the Act, announces the following appointment to the National Environmental Education Foundation Board of Trustees. The appointee is Manuel Alberto Dim, a partner in the law firm Lydecker Dim, LLP.

FOR FURTHER INFORMATION CONTACT: For information regarding this Notice of Appointment, please contact Mr. Andrew Burnett, Director, Environmental Education Division, Office of Children's Health Protection and Environmental Education (1704A) U.S. EPA, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. General information concerning NEEF can be found on their Web site at: *http://www.neefusa.org.*

SUPPLEMENTARY INFORMATION:

Additional Considerations: Great care has been taken to ensure that this new appointee not only has the highest degree of expertise and commitment, but also brings to the Board diverse points of view relating to environmental education. This appointment is a four-year term, which may be renewed for an additional four years pending successful re-election by the NEEF nominating committee.

This appointee will join the current Board members, which include:

- JL Armstrong (NEEF Vice Chair), National Manger, Toyota Motor Sales, USA, Inc.
- Raymond Ban, Executive Vice President, The Weather Channel.
- Holly Cannon, Principal, Beveridge and Diamond, P.C.
- Phillipe Cousteau, Co-Founder and CEO, EarthEcho International.
- Arthur Gibson (NEEF Chair), Vice President, Environment, Health and Safety, Baxter.
- Healthcare Corporation.
- Kenneth Olden, Chairman, Avon Foundation Scientific Advisory Board.
- Trish Silber, President, Aliniad Consulting Partners, Inc.

• Bradley Smith, Dean, Huxley College of the Environment, Western Washington University.
• Kenneth Strassner (NEEF Treasurer), Vice President, Global Environment, Safety.
• Regulatory and Scientific Affairs, Kimberly-Clark Corporation.
• Diane Wood (NEEF Secretary), President, National Environmental Education Foundation.

Background: Section 10(a) of the National Environmental Education Act of 1990 mandates a National Environmental Education Foundation. The Foundation is established in order to extend the contribution of environmental education and training to meeting critical environmental protection needs, both in this country and internationally; to facilitate the cooperation, coordination, and contribution of public and private resources to create an environmentally advanced educational system; and to foster an open and effective partnership among Federal, State and local government, business, industry, academic institutions, community-based environmental groups and international organizations.

The Foundation is a charitable and nonprofit corporation whose income is exempt from tax and donations to which are tax deductible to the same extent as those organizations listed pursuant to section 501(c) of the Internal Revenue Code of 1986. The Foundation is not an agency or establishment of the United States. The purposes of the Foundation are—

(A) Subject to the limitation contained in the final sentence of subsection (d) herein, to encourage, accept, leverage, and administer private gifts for the benefit of, or in connection with, the environmental education and training activities and services of the United States Environmental Protection Agency;

(B) To conduct such other environmental education activities as will further the development of an environmentally conscious and responsible public, a well-trained and environmentally literate workforce, and an environmentally advanced educational system;

(C) To participate with foreign entities and individuals in the conduct and coordination of activities that will further opportunities for environmental education and training to address environmental issues and problems involving the United States and Canada or Mexico.

The Foundation develops, supports, and/or operates programs and projects to educate and train educational and environmental professionals, and to assist them in the development and delivery of environmental education and training programs and studies.

The Foundation has a governing Board of Directors (hereafter referred to in this section as 'the Board'), which consists of 13 directors, each of whom shall be knowledgeable or experienced in the environment, education and/or training. The Board oversees the activities of the Foundation and ensures that the activities of the Foundation are consistent with the environmental and education goals and policies of the Environmental Protection Agency and with the intents and purposes of the Act. The membership of the Board, to the extent practicable, represents diverse points of view relating to environmental education and training. Members of the Board are appointed by the Administrator of the Environmental Protection Agency.

Within 90 days of the date of the enactment of the National Environmental Education Act, and as appropriate thereafter, the Administrator will publish in the **Federal Register** an announcement of appointments of Directors of the Board. Such appointments become final and effective 90 days after publication in the **Federal Register.** The directors are appointed for terms of 4 years. The Administrator shall appoint an individual to serve as a director in the event of a vacancy on the Board within 60 days of said vacancy in the manner in which the original appointment was made. No individual may serve more than two consecutive terms as a director.

Dated: March 11, 2010.

Lisa P. Jackson,

Administrator.

[FR Doc. 2010–8927 Filed 4–16–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9139–5]

Clean Water Act Section 303(d): Availability of One Total Maximum Daily Load (TMDL) in Arkansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of the administrative record file for comment on one TMDL and the calculations for this TMDL prepared by EPA Region 6 for waters listed in the State of Arkansas under Section 303(d) of the Clean Water Act (CWA). This TMDL was completed in response to the lawsuit styled *Sierra Club, et al.* v. *EPA, et al.,* No. LR–C–99–114.

DATES: Comments must be submitted in writing to EPA on or before May 19, 2010.

ADDRESSES: Comments on the TMDL should be sent to Ms. Diane Smith, Environmental Protection Specialist, Water Quality Protection Division, U.S. Environmental Protection Agency Region 6, 1445 Ross Ave., Dallas, TX 75202–2733, facsimile (214) 665–7373, or e-mail: *smith.diane@epa.gov*. For further information, contact Diane Smith at (214) 665–2145. Documents from the administrative record file for this TMDL are available for public inspection at this address as well. Documents from the administrative record file may be viewed at *http://www.epa.gov/region6/water/npdes/tmdl/index.htm,* or obtained by calling (214) 665–2145 or writing Ms. Smith at the above address. Please contact Ms. Smith to schedule an inspection.

FOR FURTHER INFORMATION CONTACT: Diane Smith at (214) 665–2145.

SUPPLEMENTARY INFORMATION: In 2000, five Arkansas environmental groups, the Sierra Club, Federation of Fly Fishers, Crooked Creek Coalition, Arkansas Fly Fishers, and Save our Streams (plaintiffs), filed a lawsuit in Federal Court against the EPA, styled *Sierra Club, et al.* v. *EPA, et al.,* No. LR–C–99–114. Among other claims, plaintiffs alleged that EPA failed to establish Arkansas TMDLs in a timely manner. EPA proposes this TMDL pursuant to a consent decree entered in this lawsuit.

EPA Seeks Comments on One TMDL

By this notice EPA is seeking comment on the following TMDL for waters located within the State of Arkansas:

Segment-reach	Waterbody name	Pollutant
11070208–901	Town Branch	Total Phosphorus

EPA requests that the public provide EPA with any significant water quality related data or information that may be relevant to the calculations for this TMDL. EPA will review all data and information submitted during the public comment period and revise the TMDL where appropriate. EPA will then forward the TMDL to the Arkansas Department of Environmental Quality (ADEQ). The ADEQ will incorporate the TMDL into its current water quality management plan.

Dated: April 8, 2010.

Miguel I. Flores,

Director, Water Quality Protection Division, EPA Region 6.

[FR Doc. 2010–8925 Filed 4–16–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9139–3]

National Drinking Water Advisory Council's Climate Ready Water Utilities Working Group Meeting Announcement

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) is announcing the third in-person meeting of the Climate Ready Water Utilities (CRWU) Working Group of the National Drinking Water Advisory Council (NDWAC). The purpose of this meeting is for the Working Group to discuss key findings, the adaptive response framework on what it means to be climate ready, enabling environment recommendations, and climate-related tools to support utilities.

DATES: The third in-person CRWU Working Group meeting will take place on May 5, 2010, from 8:30 a.m. to 5:30 p.m., Central Daylight Time (CDT) and on May 6, 2010, from 8:30 a.m. to 3 p.m., CDT.

ADDRESSES: The meeting will take place at the Omni Hotel Chicago, which is located at 676 North Michigan Avenue, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Interested participants from the public should contact Lauren Wisniewski, Designated Federal Officer, U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water, Water Security Division (Mail Code 4608T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please contact Lauren Wisniewski at *wisniewski.lauren@epa.gov* or call 202–564–2918. CRWU Working Group meeting agendas and summaries will be posted at: *http://www.epa.gov/safewater/ndwac/#current.*

SUPPLEMENTARY INFORMATION:

Agenda: The CRWU Working Group has developed draft key findings on the water sector and climate change, a draft adaptive response framework that describes actions that a CRWU would undertake, and draft enabling environment recommendations for activities needed to create a supportive environment in which a utility can take steps to be climate ready. The Working Group will discuss revisions and refinements to these draft report sections. Additionally, the working group will discuss tools, training, and resources needed to support water utilities and ways to integrate CRWU efforts with existing programs.

Public Participation: There will be an opportunity for public comment during the CRWU Working Group meeting. Oral statements will be limited to five minutes, and it is preferred that only one person present the statement on behalf of a group or organization. Any person who wishes to file a written statement can do so before or after the CRWU Working Group meeting. Written statements received prior to the meeting will be distributed to all members of the Working Group before any final discussion or vote is completed. Any statements received after the meeting will become part of the permanent meeting file and will be forwarded to the CRWU Working Group members for their information. For information on access or services for individuals with disabilities, please contact Lauren Wisniewski at 202–564–2918 or by e-mail at *wisniewski.lauren@epa.gov.* To request accommodation of a disability, please contact Lauren Wisniewski, preferably, at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

Background: The Agency's *National Water Program Strategy: Response to Climate Change* (2008) identified the need to provide drinking water and wastewater utilities with easy-to-use resources to assess the risk associated with climate change and to identify potential adaptation strategies. The NDWAC, established under the Safe Drinking Water Act, as amended (42 U.S.C. 300f *et seq.*), provides practical and independent advice, consultation and recommendations to the Agency on the activities, functions and policies related to the implementation of the Safe Drinking Water Act. On May 28, 2009, the NDWAC voted on and approved the formation of the CRWU Working Group. EPA anticipates that the Working Group will have five face-to-face meetings between December 2009 and September 2010 in addition to conference calls and/or video conferencing on an as needed basis. To date, there have been two face-to face meetings. After the Working Group completes its charge, it will make recommendations to the full NDWAC. The NDWAC will consider these recommendations and make its own recommendations to the EPA.

Working Group Charge: The charge for the CRWU Working Group is to evaluate the concept of "Climate Ready Water Utilities" and provide recommendations to the full NDWAC on the development of an effective program for drinking water and wastewater utilities, including recommendations to: (1) Define and develop a baseline understanding of how to use available information to develop climate change adaptation and mitigation strategies, including ways to integrate this information into existing complementary programs such as the Effective Utility Management and Climate Ready Estuaries Program; (2) Identify climate change-related tools, training, and products that address short-term and long-term needs of water and wastewater utility managers, decision makers, and engineers, including ways to integrate these tools and training into existing programs; and (3) Incorporate mechanisms to provide recognition or incentives that facilitate broad adoption of climate change adaptation and mitigation strategies by the water sector into existing EPA Office of Water recognition and awards programs or new recognition programs.

Dated: April 13, 2010.

Cynthia C. Dougherty,

Director, Office of Ground Water and Drinking Water.

[FR Doc. 2010–8929 Filed 4–16–10; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection Being Reviewed by the Federal Communications Commission, Comments Requested

April 9, 2010.

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 (PRA) of 1995, 44 U.S.C. 3501 – 3520. 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; (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, and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC 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 currently valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before June 18, 2010. 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, via fax at 202–395–5167 or via email to Nicholas_A._Fraser@omb.eop.gov and to the Federal Communications Commission via email to PRA@fcc.gov and Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Cathy Williams on (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0700.

Title: Open Video Systems Provisions, FCC Form 1275.

Form Number: FCC Form 1275.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for–profit entities; State, Local or Tribal Government.

Number of Respondents and Responses: 280 respondents and 4,672 responses.

Frequency of Response: On occasion reporting requirement; Recordkeeping and third party disclosure requirements.

Estimated Time per Response: 0.25 to 20 hours.

Total Annual Burden: 9,855 hours.

Total Annual Costs: None.

Privacy Impact Assessment: No impact(s).

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 302 of the Communications Act of 1934, as amended.

Confidentiality: No need for confidentiality required with this collection of information.

Needs and Uses: Section 302 of the 1996 Telecommunications Act provides for specific entry options for telephone companies wishing to enter the video programming marketplace, one option being to provide cable service over an "open video system" ("OVS"). The following information collection requirements listed below are covered under information collection 3060–0700.

47 CFR 76.1502(a) states an operator of an open video system must certify to the Commission that it will comply with the Commission's regulations in 47 CFR 76.1503, 76.1504, 76.1506, 76.1508, 76.1509, and 76.1513. The Commission must approve such certification prior to the commencement of service at such a point in time that would allow the applicant sufficient time to comply with the Commission's notification requirements.

47 CFR 76.1502(b) states that certifications must be verified by an officer or director of the applicant, stating that, to the best of his or her information and belief, the representations made therein are accurate.

47 CFR 75.1502(c) require that certifications must be filed on FCC Form 1275 and must include:

(1) The applicant's name, address and telephone number;

(2) A statement of ownership, including all affiliated entities;

(3) If the applicant is a cable operator applying for certification in its cable franchise area, a statement that the applicant is qualified to operate an open video system under Section 76.1501.

(4) A statement that the applicant agrees to comply and to remain in compliance with each of the Commission's regulations in §§76.1503, 76.1504, 76.1506, 76.1508, 76.1509, and 76.1513;

(5) If the applicant is required under 47 CFR 64.903(a) to file a cost allocation manual, a statement that the applicant will file changes to its manual at least 60 days before the commencement of service;

(6) A list of the names of the anticipated local communities to be served upon completion of the system;

(7) The anticipated amount and type (i.e., analog or digital) of capacity (for switched digital systems, the anticipated number of available channel input ports); and

(8) A statement that the applicant will comply with the Commission's notice and enrollment requirements for unaffiliated video programming providers.

47 CFR 76.1502(d)(1) requires that on or before the date an FCC Form 1275 is filed with the Commission, the applicant must serve a copy of its filing on all local communities identified and must include a statement informing the local communities of the Commission's requirements for filing oppositions and comments. Service by mail is complete upon mailing, but if mailed, the served documents must be postmarked at least 3 days prior to the filing of the FCC Form 1275 with the Commission.

47 CFR 76.1502(d)(2) states that parties are required to attach a cover sheet to the filing indicating that the submission is an open video system certification application. The only wording on this cover sheet shall be "Open Video System Certification Application" and "Attention: Media Bureau." This wording shall be located in the center of the page and should be in letters at least 1/2 inch in size. Parties shall also include the words "open video systems" on their mailing envelope.

47 CFR 76.1502(e)(1) requires that comments or oppositions to a certification must be filed within five calendar days of the Commission's receipt of the certification and must be served on the party that filed the certification. If, after making the necessary calculations, the due date for filing comments falls on a holiday, comments shall be filed on the next business day before noon, unless the nearest business day precedes the fifth calendar day following a filing, in which case the comments will be due on the preceding business day.

47 CFR 76.1502(e)(2) requires parties wishing to respond to a FCC Form 1275 filing must submit comments or oppositions with the Office of the Secretary and the Bureau Chief, Media Bureau. Comments will not be considered properly filed unless filed with both of these Offices. Parties are required to attach a cover sheet to the filing indicating that the submission is a pleading related to an open video system application, the only wording on this cover sheet shall be "Open Video System Certification Application Comments." This wording shall be located in the center of the page and should be in letters at least 1/2 inch in size. Parties shall also include the words "open video systems" on their mailing envelopes.

47 CFR 76.1502(f) states if the Commission does not disapprove the certification application within ten days after receipt of an applicant's request, the certification application will be deemed approved. If disapproved, the applicant may file a revised certification or refile its original submission with a statement addressing the issues in dispute. Such refilings must be served on any objecting party or parties and on

all local communities in which the applicant intends to operate. The Commission will consider any revised or refiled FCC Form 1275 to be a new proceeding and any party who filed comments regarding the original FCC Form 1275 will have to refile their original comments if they think such comments should be considered in the subsequent proceeding.

47 CFR 76.1503(b)(1) states an open video system operator shall file with the Secretary of the Federal Communications Commission a "Notice of Intent" to establish an open video system, which the Commission will release in a Public Notice. Parties are required to attach a cover sheet to the filing indicating that the submission is an Open Video System Notice of Intent. The only wording on this cover sheet shall be "Open Video System Notice of Intent" and "Attention: Media Bureau." This wording shall be located in the center of the page and should be in letters at least 1/2 inch in size. Parties shall also include the words "open video systems" on their mailing envelopes. Parties must submit copies of the Notice of Intent with the Office of the Secretary and the Bureau Chief, Media Bureau.

47 CFR 76.1503(b)(2) states that an open video system operator shall provide the following information to a video programming provider within five business days of receiving a written request from the provider, unless otherwise included in the Notice of Intent:

(i) The projected activation date of the open video system. If a system is to be activated in stages, the operator should describe the respective stages and the projected dates on which each stage will be activated;

(ii) A preliminary carriage rate estimate;

(iii) The information a video programming provider will be required to provide to qualify as a video programming provider, e.g., creditworthiness;

(iv) Technical information that is reasonably necessary for potential video programming providers to assess whether to seek capacity on the open video system, including what type of customer premises equipment subscribers will need to receive service;

(v) Any transmission or reception equipment needed by a video programming provider to interface successfully with the open video system; and

(vi) The equipment available to facilitate the carriage of unaffiliated video programming and the electronic form(s) that will be accepted for processing and subsequent transmission through the system.

47 CFR 76.1504(d) states complaints regarding rates shall be limited to video programming providers that have sought carriage on the open video system. If a video programming provider files a complaint against an open video system operator meeting the above just and reasonable rate presumption, the burden of proof will rest with the complainant. If a complaint is filed against an open video system operator that does not meet the just and reasonable rate presumption, the open video system operator will bear the burden of proof to demonstrate, using the principles set forth below, that the carriage rates subject to the complaint are just and reasonable.

47 CFR 76.1504(e) states how reasonable rates subject to complaints are determined and what tests must be met for such determinations.

47 CFR 76.1505(d)(8) states the open video system operator and/or the local franchising authority may file a complaint with the Commission, pursuant to our dispute resolution procedures set forth in § 76.1514, if the open video system operator and the local franchising authority cannot agree as to the application of the Commission's rules regarding the open video system operator's public, educational and governmental access obligations under paragraph (d) of this section.

47 CFR 76.1506(l)(2) states must–carry/retransmission consent election notifications shall be sent to the open video system operator. An open video system operator shall make all must–carry/retransmission consent election notifications received available to the appropriate programming providers on its system.

(3) Television broadcast stations are required to make the same election for open video systems and cable systems serving the same geographic area, unless the overlapping open video system is unable to deliver appropriate signals in conformance with the broadcast station's elections for all cable systems serving the same geographic area.

(4) An open video system commencing new operations shall notify all local commercial and noncommercial broadcast stations as required under paragraph (l) of this section on or before the date on which it files with the Commission its Notice of Intent to establish an open video system.

47 CFR 76.1506(m)(2) states that notification of programming to be deleted pursuant to this section shall be served on the open video system operator. The open video system operator shall make all notifications immediately available to the appropriate video programming providers on its open video system. Operators may effect the deletion of signals for which they have received deletion notices unless they receive notice within a reasonable time from the appropriate programming provider that the rights claimed are invalid. The open video system operator shall not delete signals for which it has received notice from the programming provider that the rights claimed are invalid. An open video system operator shall be subject to sanctions for any violation of this subpart. An open video system operator may require indemnification as a condition of carriage for any sanctions it may incur in reliance on a programmer's claim that certain exclusive or non–duplication rights are invalid.

47 CFR 76.1508(c) states any provision of § 76.94 that refers to a "cable system operator" or "cable television system operator" shall apply to an open video system operator. Any provision of § 76.94 that refers to a "cable system" or "cable television system" shall apply to an open video system except § 76.94 (e) and (f) which shall apply to an open video system operator. Open video system operators shall make all notifications and information regarding the exercise of network non–duplication rights immediately available to all appropriate video programming provider on the system. An open video system operator shall not be subject to sanctions for any violation of these rules by an unaffiliated program supplier if the operator provided proper notices to the program supplier and subsequently took prompt steps to stop the distribution of the infringing program once it was notified of a violation.

47 CFR 76.1509(c) states any provision of § 76.155 that refers to a "cable system operator" or "cable television system operator" shall apply to an open video system operator. Any provision of § 76.155 that refers to a "cable system" or "cable television system" shall apply to an open video system except § 76.155(c) which shall apply to an open video system operator. Open video system operators shall make all notifications and information regarding exercise of syndicated program exclusivity rights immediately available to all appropriate video programming provider on the system. An open video system operator shall not be subject to sanctions for any violation of these rules by an unaffiliated program supplier if the operator provided proper notices to the program supplier and

subsequently took prompt steps to stop the distribution of the infringing program once it was notified of a violation.

47 CFR 76.1513(a) states any party aggrieved by conduct that it believes constitute a violation of the regulations set forth in this part or in section 653 of the Communications Act (47 U.S.C. 573) may commence an adjudicatory proceeding at the Commission to obtain enforcement of the rules through the filing of a complaint. The Commission shall resolve any such dispute within 180 days after the filing of a complaint. The complaint shall be filed and responded to in accordance with the procedures specified in § 76.7 of this part with the following additions or changes.

47 CFR 76.1513(b) requires that an open video system operator may not provide in its carriage contracts with programming providers that any dispute must be submitted to arbitration, mediation, or any other alternative method for dispute resolution prior to submission of a complaint to the Commission.

47 CFR 76.1513(c) states that any aggrieved party intending to file a complaint under this section must first notify the potential defendant open video system operator that it intends to file a complaint with the Commission based on actions alleged to violate one or more of the provisions contained in this part or in Section 653 of the Communications Act. The notice must be in writing and must be sufficiently detailed so that its recipient(s) can determine the specific nature of the potential complaint. The potential complainant must allow a minimum of ten (10) days for the potential defendant(s) to respond before filing a complaint with the Commission.

47 CFR 76.1513(d) states that in addition to the requirements of § 76.7 of this part, an open video system complaint shall contain:

(1) The type of entity that describes complainant (e.g., individual, private association, partnership, or corporation), the address and telephone number of the complainant, and the address and telephone number of each defendant;

(2) If discrimination in rates, terms, and conditions of carriage is alleged, documentary evidence shall be submitted such as a preliminary carriage rate estimate or a programming contract that demonstrates a differential in price, terms or conditions between complainant and a competing video programming provider or, if no programming contract or preliminary carriage rate estimate is submitted with the complaint, an affidavit signed by an officer of complainant alleging that a differential in price, terms or conditions exists, a description of the nature and extent (if known or reasonably estimated by the complainant) of the differential, together with a statement that defendant refused to provide any further specific comparative information;

Note to paragraph (d)(2): Upon request by a complainant, the preliminary carriage rate estimate shall include a calculation of the average of the carriage rates paid by the unaffiliated video programming providers receiving carriage from the open video system operator, including the information needed for any weighting of the individual carriage rates that the operator has included in the average rate.

(3) If a programming contract or a preliminary carriage rate estimate is submitted with the complaint in support of the alleged violation, specific references to the relevant provisions therein.

(4) The complaint must be accompanied by appropriate evidence demonstrating that the required notification pursuant to paragraph (c) of this section has been made.

47 CFR 76.1513(e)(1) requires that any open video system operator upon which a complaint is served under this section shall answer within thirty (30) days of service of the complaint, unless otherwise directed by the Commission.

47 CFR 76.1513(e)(2) states that an answer to a discrimination complaint shall state the reasons for any differential in prices, terms or conditions between the complainant and its competitor, and shall specify the particular justification relied upon in support of the differential. Any documents or contracts submitted pursuant to this paragraph may be protected as proprietary pursuant to § 76.9 of this part.

47 CFR 76.1513(f) states that within twenty (20) days after service of an answer, the complainant may file and serve a reply which shall be responsive to matters contained in the answer and shall not contain new matters.

47 CFR 76.1513(g) requires that any complaint filed pursuant to this subsection must be filed within one year of the date on which one of the following events occurs:

(1) The open video system operator enters into a contract with the complainant that the complainant alleges to violate one or more of the rules contained in this part; or

(2) The open video system operator offers to carry programming for the complainant pursuant to terms that the complainant alleges to violate one or more of the rules contained in this part, and such offer to carry programming is unrelated to any existing contract between the complainant and the open video system operator; or

(3) The complainant has notified an open video system operator that it intends to file a complaint with the Commission based on a request for such operator to carry the complainant's programming on its open video system that has been denied or unacknowledged, allegedly in violation of one or more of the rules contained in this part.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2010–8818 Filed 4–16–10; 8:45 am]

BILLING CODE: 6712–01–S

FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act Meeting; Open Commission Meeting; April 21, 2010

Date: April 14, 2010.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Wednesday, April 21, 2010, which is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street, S.W., Washington, D.C.

In accordance with the purpose of the Sunshine period, comments submitted on blog pages in broadband.gov during the Sunshine period will not be considered by the Commission in finalizing the items under consideration at the open meeting on April 21.

ITEM NO.	BUREAU	SUBJECT
1	WIRELINE COMPETITION	TITLE: Connect America Fund; A National Broadband Plan for Our Future (GN Docket No 09–51); and High–Cost Universal Service Support (WC Docket No. 05–337) SUMMARY: The Commission will consider a Notice of Inquiry and Notice of Proposed Rulemaking initiating universal service reforms as outlined in the National Broadband Plan and Joint Statement on Broadband.
2	WIRELESS TELE–COMMUNICATIONS	TITLE: Reexamination of Roaming Obligations of Commercial Mobile Radio Service Providers and Other Providers of Mobile Data Services (WT Docket No. 05–265) SUMMARY: The Commission will consider an Order on Reconsideration regarding automatic voice roaming requirements and a Second Further Notice of Proposed Rulemaking regarding automatic roaming for mobile data services.
3	MEDIA	TITLE: Video Device Competition; Implementation of Section 304 of the Telecommunications Act of 1996: Commercial Availability of Navigation Devices (CS Docket No. 97–80); and Compatibility Between Cable Systems and Consumer Electronics Equipment (PP Docket No. 00–67) SUMMARY: The Commission will consider a Notice of Inquiry seeking comment on best approaches to assure the commercial availability of smart video devices and other equipment used to access the services of multichannel video programming distributors.
4	MEDIA	TITLE: Implementation of Section 304 of the Telecommunications Act of 1996: Commercial Availability of Navigation Devices(CS Docket No. 97–80); and Compatibility Between Cable Systems and Consumer Electronics Equipment (PP Docket No. 00–67) SUMMARY: The Commission will consider a Fourth Further Notice of Proposed Rulemaking that proposes changes to the CableCARD rules for set–top boxes used with cable services, to improve the operation of that framework pending the development of a successor framework.
5	PUBLIC SAFETY & HOMELAND SECURITY	TITLE: Effects on Broadband Communications Networks Of Damage to or Failure of Network Equipment Or Severe Overload SUMMARY: The Commission will consider a Notice of Inquiry that examines the survivability of broadband infrastructure and seeks comment on the ability of existing broadband networks to withstand significant damage or severe overloads as result of natural disasters, terrorist attacks, pandemics or other major public emergencies.
6	PUBLIC SAFETY & HOMELAND SECURITY	TITLE: Cyber Security Certification Program SUMMARY: The Commission will consider a Notice of Inquiry on whether to establish a voluntary cyber security certification program.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an e–mail to: fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Additional information concerning this meeting may be obtained from Audrey Spivack or David Fiske, Office of Media Relations, (202) 418–0500;

TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live web page at www.fcc.gov/live.

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services call (703) 993–3100 or go to www.capitolconnection.gmu.edu.

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, Best Copy and Printing, Inc. (202) 488–5300; Fax (202) 488–5563; TTY (202) 488–5562. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio and video tape. Best Copy and Printing, Inc. may be reached by e–mail at FCC@BCPIWEB.com.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2010–9097 Filed 4–15–10; 8:45 am]

BILLING CODE 6712–01–S

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Revision of Information Collection; National Survey of Unbanked and Underbanked Households; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden and as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), invites the general public and other Federal agencies to comment on the survey collection instrument for its second National Survey of Unbanked and Underbanked Households ("Household Survey"), currently approved under OMB Control No. 3064–0167, scheduled to be conducted in partnership with the U.S. Census Bureau as a supplement to its June 2011 Current Population Survey ("CPS"). The collection is a key component of the FDIC's efforts to comply with a Congressional mandate contained in section 7 of the Federal Deposit Insurance Reform Conforming Amendments Act of 2005 ("Reform Act") (Pub. L. 109–173), which calls for the FDIC to conduct ongoing surveys "on efforts by insured depository institutions to bring those individuals and families who have rarely, if ever, held a checking account, a savings account or other type of transaction or check cashing account at an insured depository institution (hereafter in this section referred to as the 'unbanked') into the conventional finance system." Section 7 further instructs the FDIC to consider several factors in its conduct of the surveys, including: (1) "What cultural, language and identification issues as well as transaction costs appear to most prevent 'unbanked' individuals from establishing conventional accounts"; and (2) "what is a fair estimate of the size and worth of the 'unbanked' market in the United States." The household survey is designed to address these factors and provide a factual basis on the proportions of unbanked households. Such a factual basis is necessary to adequately assess banks' efforts to serve these households as required by the statutory mandate.

To satisfy the Congressional mandate, the FDIC designed two complementary surveys: a survey of FDIC-insured depository institutions and a survey of households. The first survey of FDIC-insured depository institutions, aimed at collecting data on their efforts to serve underbanked, as well as unbanked, populations (underbanked populations include individuals who have an account with an insured depository but also rely on non-bank alternative financial service providers for transaction services or high cost credit products), was conducted in mid-2007, with the results released in February 2008. The first survey of unbanked and underbanked households was conducted in January 2009 as a CPS supplement and the results were released to the public in December 2009. The household survey sought to estimate the proportions of unbanked and underbanked households in the U.S. and to identify the factors that inhibit the participation of these households in the mainstream banking system. The results of these ongoing surveys will help policymakers and bankers understand the issues and challenges underserved households perceive when deciding how and where to conduct financial transactions. This notice addresses the next Household Survey.

DATES: Comments must be submitted on or before June 18, 2010.

ADDRESSES: Interested parties are invited to submit written comments by any of the following methods. All comments should refer to "National Survey of Unbanked and Underbanked Households":

- *http://www.FDIC.gov/regulations/laws/federal/*.
- *E-mail: comments@fdic.gov*. Include the name and number of the collection in the subject line of the message.
- *Mail:* Leneta Gregorie (202–898–3719), Counsel, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 550 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Interested members of the public may obtain a copy of the survey and related instructions by clicking on the link for the *National Unbanked and Underbanked Household Survey* on the following Web page: *http://www.fdic.gov/regulations/laws/federal/notices.html*. Interested members of the public may also obtain additional information about the collection, including a paper copy of the proposed collection and related instructions, without charge, by contacting Leneta Gregorie at the address identified above, or by calling (202) 898–3719.

SUPPLEMENTARY INFORMATION: The FDIC is considering possible revisions to the following collection of information:

Title: National Unbanked and Underbanked Household Survey.

OMB Number: 3064–0167.

Frequency of Response: Once.

Affected Public: U.S. Households.

Estimated Number of Respondents: 50,000.

Average time per response: 10 minutes (0.166 hours) per respondent.

Estimated Total Annual Burden: 0.166 hours × 50,000 respondents = 8,334 hours.

General Description of Collection

A mandate in section 7 of the Reform Act requires the FDIC to conduct ongoing surveys on efforts by banks to bring unbanked individuals and families into the conventional finance system. Section 7 further instructs the FDIC to consider several factors in its conduct of the surveys, including the size of the unbanked market in the United States and the cultural, language and identification issues as well as transaction costs that appear to most prevent unbanked individuals from establishing conventional accounts. To obtain this information, the FDIC partnered with the U.S. Census Bureau, which administered the Household Survey supplement ("FDIC

Supplement") to households that participated in the January 2009 CPS. The FDIC supplement has yielded significant data on the extent and demographic characteristics of the population that is unbanked or underbanked, the use by this population of alternative financial services, and the reasons why some households do not make greater use of traditional banking services. The Household Survey was the first survey of its kind to be conducted at the national level. An executive summary of the results of the Household Survey, the full report, and the survey instrument can be accessed through the following link: *http://www.economicinclusion.gov/about_survey.html.*

Consistent with the statutory mandate to conduct the surveys on an ongoing basis, the FDIC already has in place arrangements for conduct of its second Household Survey as a supplement to the June 2011 CPS. However, prior to finalizing the next survey instrument, the FDIC seeks to solicit public comment on whether changes to the existing instrument are desirable and, if so, to what extent. It should be noted that, as a supplement of the CPS survey, the Household Survey needs to adhere to specific parameters that include limits in the length and sensitivity of the questions that can be asked of CPS respondents. Specifically, there is a strict limitation on the number of questions permitted (no more than 32) and the average time required to complete the survey (10 minutes on average).

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

The FDIC will consider all comments to determine the extent to which the information collection should be modified prior to submission to OMB for review and approval. After the comment period closes, comments will be summarized and/or included in the FDIC's request to OMB for approval of the collection. All comments will become a matter of public record.

Dated at Washington, DC, this 13th day of April 2010.

Federal Deposit Insurance Corporation.

Robert F. Feldman,

Executive Secretary.

[FR Doc. 2010–8913 Filed 4–16–10; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Intra-Agency Appeal Process: Guidelines for Appeals of Material Supervisory Determinations and Guidelines for Appeals of Deposit Insurance Assessment Determinations

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Notice of guidelines.

SUMMARY: On April 13, 2010, the Federal Deposit Insurance Corporation ("FDIC") Board of Directors ("Board") adopted revised Guidelines for Appeals of Material Supervisory Determinations ("SARC Guidelines"). The SARC Guidelines govern the Supervision Appeals Review Committee ("SARC") process and supersede the FDIC's prior SARC Guidelines, which were adopted by the FDIC's Board of Directors on September 16, 2008. In addition, on April 13, 2010, the Board also adopted revised Guidelines for Appeals of Deposit Insurance Assessment Determinations ("AAC Guidelines"), which govern the Assessment Appeals Committee ("AAC") process and supersede the FDIC's prior AAC Guidelines, which were adopted on June 28, 2004. The SARC Guidelines have been amended to extend the decision deadline for requests for review and to clarify the decisional deadline for written decisions by the SARC. Also, both the SARC Guidelines and the AAC Guidelines have been amended to make additional, limited technical clarifying and conforming amendments. Both sets of revised guidelines are effective upon adoption.

DATES: The revised SARC Guidelines and the revised AAC Guidelines became effective on April 13, 2010.

For Further Information Concerning the SARC Guidelines Contact: Patricia Colohan, Acting Associate Director, Division of Supervision and Consumer Protection, (202) 898–7283; Richard Bogue, Counsel, Legal Division, (202) 898–3726; Jeannette E. Roach, Counsel, Legal Division, (202) 898–3785, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

For Further Information Concerning the AAC Guidelines Contact: Christopher Bellotto, Counsel, (202) 898–3801, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Background

1. Guidelines for Appeals of Material Supervisory Determinations

Section 309(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 (Pub. L. 103–325, 108 Stat. 2160) ("Riegle Act") required the FDIC (as well as the other Federal banking agencies and the National Credit Union Administration Board) to establish an independent intra-agency appellate process to review material supervisory determinations.

The Riegle Act defines the term "independent appellate process" to mean a review by an agency official who does not directly or indirectly report to the agency official who made the material supervisory determination under review. In the appeals process, the FDIC is required to ensure that (1) an appeal of a material supervisory determination by an insured depository institution is heard and decided expeditiously; and (2) appropriate safeguards exist for protecting appellants from retaliation by agency examiners.

On March 21, 1995, the FDIC's Board of Directors adopted the original Guidelines for Appeals of Material Supervisory Determinations, which established and set forth procedures governing the SARC, whose purpose was to consider and decide appeals of material supervisory determinations as required by the Riegle Act. The SARC Guidelines were amended, after notice and comment, on July 9, 2004, adopting revised Guidelines and changing the composition and procedures of the SARC. (69 FR 41479 (July 9, 2004)).

The SARC Guidelines were amended again in 2008, after notice and comment, to modify the supervisory determinations eligible for appeal to eliminate the ability of an FDIC-supervised institution to file an appeal with the SARC with respect to determinations or the facts and circumstances underlying a recommended or pending formal enforcement-related action or decision, and to make limited technical amendments. (73 FR 54822 (Sept. 23, 2008)).

Although the FDIC considered it desirable in those instances to garner comments regarding the Guidelines, notice and comment rulemaking was not required, and the FDIC pointed out that notice and comment rulemaking need not be employed in making future

amendments. Notice and comment rulemaking was not employed in making the present amendments.

2. Guidelines for Appeals of Deposit Insurance Assessment Determinations

The FDIC Board of Directors created the AAC in 1999 to provide a high-level process for considering all deposit insurance assessment appeals brought from determinations made by the appropriate FDIC Divisions. Responsibility for deposit insurance assessments is shared by the Division of Finance ("DOF"), the Division of Insurance and Research ("DIR") and, in some respects, the Division of Supervision and Consumer Protection ("DSC"). DOF is responsible for calculating the assessments owed by individual insured institutions based on assessment risk rates assigned by DIR, which in turn uses supervisory information provided by DSC.

Institutions that dispute the computation of their quarterly assessment payments may request revision of their assessment payments by following the procedures set forth at 12 CFR 327.3(f). Institutions that dispute their risk assignment—or dispute any determination for which review may be requested as provided in Part 327—may request review by following the procedures set forth at 12 CFR 327.4(c).

The AAC provides a process for considering all deposit insurance assessment appeals brought from determinations made by the appropriate FDIC divisions pursuant to 12 CFR 327.3(f) and 327.4(c). Having complied with those procedures and received a determination from the appropriate division, an institution dissatisfied with that division's determination may file an appeal with the AAC. After reviewing the determination made at the division level, the AAC will issue a final decision.

The AAC Guidelines were promulgated by the FDIC on July 2, 2004, following notice and comment rulemaking. (69 FR 41479 (July 9, 2004)). Although the FDIC considered it desirable in that instance to garner comments regarding the AAC Guidelines, notice and comment rulemaking was not required, and the FDIC pointed out that notice and comment rulemaking need not be employed in making future amendments. Notice and comment rulemaking was not employed in making the present amendments.

Amendments to the Guidelines

The SARC Guidelines provide that following an institution's filing of a request for review of a material supervisory determination with the Director of DSC, the Director "will issue a written determination of the request for review, setting forth the grounds for that determination, within 30 days of receipt of the request." Paragraph F(b). This deadline has proven to provide insufficient time for the issuance of a determination following the necessary analysis of the request and coordination between FDIC divisions and offices charged with carrying out the appeals process. To provide the necessary time, this language has been amended to provide that the Director will issue the written determination "within 45 days of receipt of the request."

The SARC Guidelines provided that written decisions of the SARC were to be issued "within 60 days from the date the appeal is filed, or within 60 days from oral presentation, if held." It was contemplated that oral presentations would be made at SARC meetings to aid the Committee in issuing written decisions within 60 days thereafter. The prior language of the SARC Guidelines (paragraph M), however, contemplated a period of less than 60 days after the SARC met in which the Committee was to issue a decision in cases where no oral presentation was held. To clarify the decisional deadline for the Committee, the prior language has been amended to provide that, whether or not oral presentation has been held, the SARC will issue a decision "within 45 days from the date the SARC meets to consider the appeal, which meeting will be held within 90 days from the date of the filing of the appeal."

At various places throughout both the SARC Guidelines and AAC Guidelines, minor modifications of language are made to standardize references to FDIC divisions and FDIC officials who are charged with carrying out the appeals processes. In addition, where the FDIC's regulations have been amended since the AAC Guidelines were promulgated, the current regulatory citations have been provided.

Paragraph E of the AAC Guidelines (Appeal to the AAC) provides that a division director may, with the approval of the Chairperson of the AAC, transfer a request for review or request for revision directly to the AAC if the director lacks delegated authority to grant relief. In order to further facilitate the prompt resolution of such requests for review or requests for revision, a mechanism through which a division director may seek guidance from the AAC Chairperson has been added to Paragraph E, which conforms to similar, current language at Paragraph G of the SARC Guidelines. In addition, both Paragraph E of the AAC Guidelines and Paragraph G of the SARC Guidelines have been amended to provide that a division director's request to transfer a matter directly to the SARC or AAC will be done on the director's recommendation, rather than the director's determination, since no determination will have been made.

Paragraph L of the AAC Guidelines (Publication of Decisions) provides that published AAC decisions will be redacted to avoid the disclosure of exempt information. Because there may be circumstances where no amount of redaction of the full-text AAC decision would be sufficient to prevent improper disclosure while at the same time providing a meaningful statement of what the AAC has decided, Paragraph L has been revised to provide for summary form publication where redaction is deemed to be insufficient to prevent improper disclosure. This amendment mirrors a change made to the corresponding Paragraph N of the SARC Guidelines in 2008.

For the reasons stated in the Preamble, the Board has adopted the Guidelines for Appeals of Material Supervisory Determinations and the Guidelines for Appeals of Deposit Insurance Assessment Determinations as set forth below.

Guidelines for Appeals of Material Supervisory Determinations

A. Introduction

Section 309(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 (Pub. L. 103–325, 108 Stat. 2160) ("Riegle Act") required the Federal Deposit Insurance Corporation ("FDIC") to establish an independent intra-agency appellate process to review material supervisory determinations made at insured depository institutions that it supervises. The Guidelines for Appeals of Material Supervisory Determinations ("guidelines") describe the types of determinations that are eligible for review and the process by which appeals will be considered and decided. The procedures set forth in these guidelines establish an appeals process for the review of material supervisory determinations by the Supervision Appeals Review Committee ("SARC").

B. SARC Membership

The following individuals comprise the three (3) voting members of the SARC: (1) One inside FDIC Board member, either the Chairperson, the Vice Chairperson, or the FDIC Director (Appointive), as designated by the FDIC Chairperson (this person would serve as

the Chairperson of the SARC); and (2) one deputy or special assistant to each of the inside FDIC Board members who are not designated as the SARC Chairperson. The General Counsel is a non-voting member of the SARC. The FDIC Chairperson may designate alternate member(s) to the SARC if there are vacancies so long as the alternate member was not involved in making or affirming the material supervisory determination under review. A member of the SARC may designate and authorize the most senior member of his or her staff within the substantive area of responsibility related to cases before the SARC to act on his or her behalf.

C. Institutions Eligible To Appeal

The guidelines apply to the insured depository institutions that the FDIC supervises (*i.e.,* insured State nonmember banks and insured branches of foreign banks) and also to other insured depository institutions with respect to which the FDIC makes material supervisory determinations.

D. Determinations Subject To Appeal

An institution may appeal any material supervisory determination pursuant to the procedures set forth in these guidelines. Material supervisory determinations include:

(a) CAMELS ratings under the Uniform Financial Institutions Rating System;

(b) IT ratings under the Uniform Interagency Rating System for Data Processing Operations;

(c) Trust ratings under the Uniform Interagency Trust Rating System;

(d) CRA ratings under the Revised Uniform Interagency Community Reinvestment Act Assessment Rating System;

(e) Consumer compliance ratings under the Uniform Interagency Consumer Compliance Rating System;

(f) Registered transfer agent examination ratings;

(g) Government securities dealer examination ratings;

(h) Municipal securities dealer examination ratings;

(i) Determinations relating to the adequacy of loan loss reserve provisions;

(j) Classifications of loans and other assets in dispute the amount of which, individually or in the aggregate, exceeds 10 percent of an institution's total capital;

(k) Determinations relating to violations of a statute or regulation that may impact the capital, earnings, or operating flexibility of an institution, or otherwise affect the nature and level of supervisory oversight accorded an institution;

(l) Truth in Lending (Regulation Z) restitution;

(m) Filings made pursuant to 12 CFR 303.11(f), for which a Request for Reconsideration has been granted, other than denials of a change in bank control, change in senior executive officer or board of directors, or denial of an application pursuant to section 19 of the FDI Act (which are contained in 12 CFR 308, subparts D, L, and M, respectively), if the filing was originally denied by the Director, Deputy Director, or Associate Director of the Division of Supervision and Consumer Protection; and

(n) Any other supervisory determination (unless otherwise not eligible for appeal) that may impact the capital, earnings, operating flexibility, or capital category for prompt corrective action purposes of an institution, or otherwise affect the nature and level of supervisory oversight accorded an institution.

Material supervisory determinations do not include:

(a) Decisions to appoint a conservator or receiver for an insured depository institution;

(b) Decisions to take prompt corrective action pursuant to section 38 of the Federal Deposit Insurance Act, 12 U.S.C. 1831o;

(c) Determinations for which other appeals procedures exist (such as determinations of deposit insurance assessment risk classifications and payment calculations);

(d) Decisions to initiate informal enforcement actions (such as memoranda of understanding); and

(e) Formal enforcement-related actions and decisions, including determinations and the underlying facts and circumstances that form the basis of a recommended or pending formal enforcement action, and FDIC determinations regarding compliance with an existing formal enforcement action.

A formal enforcement-related action or decision commences, and therefore becomes unappealable, when the FDIC initiates a formal investigation under 12 U.S.C. 1820(c) or provides written notice to the bank indicating its intention to pursue available formal enforcement remedies under applicable statutes or published enforcement-related policies of the FDIC, including written notice of a referral to the Attorney General or a notice to the Secretary of Housing and Urban Development for violations of the Equal Credit Opportunity Act or the Fair Housing Act. For the purposes of these guidelines, remarks in a Report of Examination do not constitute written notice of intent to pursue formal enforcement remedies.

E. Good-Faith Resolution

An institution should make a good-faith effort to resolve any dispute concerning a material supervisory determination with the on-site examiner and/or the appropriate Regional Office. The on-site examiner and the Regional Office will promptly respond to any concerns raised by an institution regarding a material supervisory determination. Informal resolution of disputes with the on-site examiner and/or the appropriate Regional Office is encouraged, but seeking such a resolution is not a condition to filing a request for review with the Division of Supervision and Consumer Protection or an appeal to the SARC under these guidelines.

F. Filing a Request for Review With the FDIC Division of Supervision and Consumer Protection

An institution may file a request for review of a material supervisory determination with the Director, Division of Supervision and Consumer Protection ("Director" or "Division Director"), 550 17th Street, NW., Room F–4076, Washington, DC 20429, within 60 calendar days following the institution's receipt of a report of examination containing a material supervisory determination or other written communication of a material supervisory determination. A request for review must be in writing and must include:

(a) A detailed description of the issues in dispute, the surrounding circumstances, the institution's position regarding the dispute and any arguments to support that position (including citation of any relevant statute, regulation, policy statement, or other authority), how resolution of the dispute would materially affect the institution, and whether a good-faith effort was made to resolve the dispute with the on-site examiner and the Regional Office; and

(b) A statement that the institution's board of directors has considered the merits of the request and authorized that it be filed.

The Division Director will issue a written determination of the request for review, setting forth the grounds for that determination, within 45 days of receipt of the request. No appeal to the SARC will be allowed unless an institution has first filed a timely request for review with the Division of Supervision and Consumer Protection.

G. Appeal to the SARC

An institution that does not agree with the written determination rendered by the Division Director must appeal that determination to the SARC within 30 calendar days from the date of that determination. The Director's determination will inform the institution of the 30-day time period for filing with the SARC and will provide the mailing address for any appeal the institution may wish to file. Failure to file within the 30-day time limit may result in denial of the appeal by the SARC. If the Division Director recommends that an institution receive relief that the Director lacks delegated authority to grant, the Director may, with the approval of the Chairperson of the SARC, transfer the matter directly to the SARC without issuing a determination. Notice of such a transfer will be provided to the institution. The Division Director may also request guidance from the SARC Chairperson as to procedural or other questions relating to any request for review.

H. Filing With the SARC

An appeal to the SARC will be considered filed if the written appeal is received by the FDIC within 30 calendar days from the date of the Division Director's written determination or if the written appeal is placed in the U.S. mail within that 30-day period. If the 30th day after the date of the Division Director's written determination is a Saturday, Sunday, or Federal holiday, filing may be made on the next business day. The appeal should be sent to the address indicated on the Division Director's determination being appealed.

I. Contents of Appeal

The appeal should be labeled to indicate that it is an appeal to the SARC and should contain the name, address, and telephone number of the institution and any representative, as well as a copy of the Division Director's determination being appealed. If oral presentation is sought, that request should be included in the appeal. Only matters previously reviewed at the division level, resulting in a written determination or direct referral to the SARC, may be appealed to the SARC. Evidence not presented for review to the Division Director may be submitted to the SARC only if authorized by the SARC Chairperson. The institution should set forth all of the reasons, legal and factual, why it disagrees with the Division Director's determination. Nothing in the SARC administrative process shall create any discovery or other such rights.

J. Burden of Proof

The burden of proof as to all matters at issue in the appeal, including timeliness of the appeal if timeliness is at issue, rests with the institution.

K. Oral Presentation

The SARC may, in its discretion, whether or not a request is made, determine to allow an oral presentation. The SARC generally grants a request for oral presentation if it determines that oral presentation is likely to be helpful or would otherwise be in the public interest. Notice of the SARC's determination to grant or deny a request for oral presentation will be provided to the institution. If oral presentation is held, the institution will be allowed to present its positions on the issues raised in the appeal and to respond to any questions from the SARC. The SARC may also require that FDIC staff participate as the SARC deems appropriate.

L. Dismissal, Withdrawal and Rejection

An appeal may be dismissed by the SARC if it is not timely filed, if the basis for the appeal is not discernable from the appeal, or if the institution moves to withdraw the appeal. An appeal may be rejected if the right to appeal has been cut off under Section D, above.

M. Scope of Review and Decision

The SARC will review the appeal for consistency with the policies, practices and mission of the FDIC and the overall reasonableness of and the support offered for the positions advanced, and notify the institution, in writing, of its decision concerning the disputed material supervisory determination(s) within 45 days from the date the SARC meets to consider the appeal, which meeting will be held within 90 days from the date of the filing of the appeal. SARC review will be limited to the facts and circumstances as they existed prior to or at the time the material supervisory determination was made, even if later discovered, and no consideration will be given to any facts or circumstances that occur or corrective action taken after the determination was made. The SARC may reconsider its decision only on a showing of an intervening change in the controlling law or the availability of material evidence not reasonably available when the decision was issued.

N. Publication of Decisions

SARC decisions will be published, and the published SARC decisions will be redacted to avoid disclosure of exempt information. In cases where redaction is deemed to be insufficient to prevent improper disclosure, published decisions may be presented in summary form. Published SARC decisions may be cited as precedent in appeals to the SARC.

O. SARC Guidelines Generally

Appeals to the SARC will be governed by these guidelines. The SARC will retain the discretion to waive any provision of the guidelines for good cause; the SARC may adopt supplemental rules governing SARC operations; the SARC may order that material be kept confidential; and the SARC may consolidate similar appeals.

P. Limitation on Agency Ombudsman

The subject matter of a material supervisory determination for which either an appeal to the SARC has been filed or a final SARC decision issued is not eligible for consideration by the Ombudsman.

Q. Coordination With State Regulatory Authorities

In the event that a material supervisory determination subject to a request for review is the joint product of the FDIC and a State regulatory authority, the Director, Division of Supervision and Consumer Protection, will promptly notify the appropriate State regulatory authority of the request, provide the regulatory authority with a copy of the institution's request for review and any other related materials, and solicit the regulatory authority's views regarding the merits of the request before making a determination. In the event that an appeal is subsequently filed with the SARC, the SARC will notify the institution and the State regulatory authority of its decision. Once the SARC has issued its determination, any other issues that may remain between the institution and the State authority will be left to those parties to resolve.

R. Effect on Supervisory or Enforcement Actions

The use of the procedures set forth in these guidelines by any institution will not affect, delay, or impede any formal or informal supervisory or enforcement action in progress or affect the FDIC's authority to take any supervisory or enforcement action against that institution.

S. Effect on Applications or Requests for Approval

Any application or request for approval made to the FDIC by an

institution that has appealed a material supervisory determination that relates to or could affect the approval of the application or request will not be considered until a final decision concerning the appeal is made unless otherwise requested by the institution.

T. Prohibition on Examiner Retaliation

The FDIC has an experienced examination workforce and is proud of its professionalism and dedication. FDIC policy prohibits any retaliation, abuse, or retribution by an agency examiner or any FDIC personnel against an institution. Such behavior against an institution that appeals a material supervisory determination constitutes unprofessional conduct and will subject the examiner or other personnel to appropriate disciplinary or remedial action. Institutions that believe they have been retaliated against are encouraged to contact the Regional Director for the appropriate FDIC region. Any institution that believes or has any evidence that it has been subject to retaliation may file a complaint with the Director, Office of the Ombudsman, Federal Deposit Insurance Corporation, 550 17th Street, Washington, DC 20429, explaining the circumstances and the basis for such belief or evidence and requesting that the complaint be investigated and appropriate disciplinary or remedial action taken. The Office of the Ombudsman will work with the Division of Supervision and Consumer Protection to resolve the allegation of retaliation.

Guidelines for Appeals of Deposit Insurance Assessment Determinations

A. Introduction

The Assessment Appeals Committee ("AAC") was formed in 1999 and, pursuant to the direction of the FDIC Board of Directors, has been functioning as the appellate entity responsible for making final determinations pursuant to Part 327 of the FDIC's regulations regarding the assessment risk assignment, the assessment payment computation, and other related assessment determinations affecting insured depository institutions. Institutions that dispute the computation of their quarterly assessment payments must comply with the time limits and other filing requirements set forth at 12 CFR 327.3(f). Generally, any such request may be made within 90 days of the quarterly assessment invoice for which a revision is requested. Institutions that dispute their risk assignment—or dispute any determination for which review may be requested as provided in part 327—must comply with the time limits and other filing requirements set forth at 12 CFR 327.4(c). Generally, an institution may request review within 90 days from the date it receives notice of its risk assignment or other disputed determination from the FDIC. The AAC provides a process for considering all deposit insurance assessment appeals brought from determinations made by the appropriate FDIC divisions pursuant to 12 CFR 327.3(f) and 327.4(c). The procedures set forth in these guidelines apply to all appeals to the AAC.

B. AAC Membership

The following individuals comprise the five (5) voting members of the AAC, representing each member of the FDIC Board of Directors: (1) One inside FDIC Board member, either the Vice Chairperson or the Director (Appointive), as designated by the FDIC Chairperson (this person would serve as Chairperson of the AAC); (2) one of the deputies or special assistants to the FDIC Chairperson, to be designated by the FDIC Chairperson; (3) a deputy or special assistant to the Office of the Comptroller of the Currency's member on the FDIC's Board of Directors; (4) a deputy or special assistant to the Office of Thrift Supervision's member on the FDIC's Board of Directors; and (5) a deputy or special assistant to either the Vice Chairperson or the inside Director (Appointive), whoever is not the AAC Chairperson. The General Counsel is a non-voting member of the AAC. The FDIC Chairperson may designate alternative member(s) for the AAC if vacancies occur. A member of the AAC may designate and authorize the most senior member of his or her staff within the substantive area of responsibility related to cases before the AAC to act on his or her behalf.

C. Institutions Eligible to Appeal

These guidelines apply to all depository institutions insured by the FDIC.

D. Determinations Subject to Appeal

The AAC, upon appeal by an insured depository institution, reviews determinations of the Director of the Division of Insurance and Research or the Director of the Division of Supervision and Consumer Protection made pursuant to the procedures set forth at 12 CFR 327.4(c) regarding the assessment risk assignment provided by the FDIC to the institution—or any determination for which review may be requested as provided in Part 327—and renders a final determination. The AAC also, upon appeal by an insured depository institution, reviews determinations made pursuant to 12 CFR 327.3(f) by the Director of the Division of Finance regarding the computation of the institution's assessment payment and renders a final determination.

E. Appeal to the AAC

An institution that does not agree with the written determination rendered by the appropriate Division Director pursuant to 12 CFR 327.4(c) and 327.3(f) must appeal that determination to the AAC within 30 calendar days from the date of the determination. The division director's determination will inform the institution of the 30-day time limit for filing with the AAC and will provide the mailing address for any appeal the institution may wish to file. Failure to file within the 30-day time period may result in denial of the appeal by the AAC.

If a Division Director recommends that an institution receive relief that the Director lacks delegated authority to grant, the Director may, with the approval of the Chairperson of the AAC, transfer the matter directly to the AAC without issuing a determination. Notice of such a transfer will be provided to the institution. A Division Director may also request guidance from the AAC Chairperson as to procedural or other questions relating to any request for revision or request for review.

F. Filing With the AAC

An appeal to the AAC will be considered filed if the written appeal is received by the FDIC within 30 calendar days from the date of the Division Director's written determination or if the written appeal is placed in the U.S. mail within that 30-day period. If the 30th day after the date of the Division Director's written determination is a Saturday, Sunday or Federal holiday, filing may be made on the next business day. The appeal should be sent to the address indicated on the determination being appealed.

G. Contents of Appeal

The appeal should be labeled to indicate that it is an appeal to the AAC and should contain the name, address, and telephone number of the institution and any representative, as well as a copy of the determination being appealed. If oral presentation is sought, that request should be included in the appeal. Only matters previously reviewed at the division level, resulting in either a written determination or a direct referral to the AAC, may be appealed to the AAC. Evidence not presented for review at the division level may be submitted to the AAC only

if authorized by the AAC Chairperson. The institution should set forth all of the reasons, legal and factual, why it disagrees with the determination. Nothing in the AAC administrative process shall create any discovery or other such rights.

H. Burden of Proof

The burden of proof as to all matters at issue in the appeal, including timeliness of the appeal if timeliness is at issue, rests with the institution.

I. Oral Presentation

The AAC may, in its discretion, whether or not a request is made, determine to allow an oral presentation. The AAC generally grants a request for oral presentation if it determines that oral presentation is likely to be helpful or would otherwise be in the public interest. Notice of the AAC's determination to grant or deny a request for oral presentation will be provided to the institution. If oral presentation is held, the institution will be allowed to present its position on the issues raised in the appeal and to respond to any questions from the AAC. The AAC may also require that FDIC staff participate as the AAC deems appropriate.

J. Dismissal and Withdrawal

An appeal may be dismissed by the AAC if it is not timely filed, if the legal or factual basis for the appeal is not discernable from the appeal, or if the institution moves to withdraw the appeal.

K. Scope of Review and Decision

The AAC will review all submissions concerning an appeal, review the final determination being appealed, consider any other matters it deems in its discretion to be appropriate, and issue a written decision within 60 days from the date the appeal is filed, or within 60 days from oral presentation, if held. The AAC may reconsider its decision only on a showing of an intervening change in the controlling law or the availability of material evidence not reasonably available when the decision was issued.

L. Publication of Decisions

AAC decisions will be published and the published AAC decisions will be redacted to avoid disclosure of exempt information. In cases where redaction is deemed to be insufficient to prevent improper disclosure, published decisions may be presented in summary form. Published decisions of the AAC may be cited as precedent in appeals to the AAC.

M. AAC Guidelines Generally

Appeals to the AAC will be governed by these guidelines. The AAC will retain the discretion to waive any provision of the guidelines for good cause; the AAC may adopt supplemental rules governing AAC operations; the AAC may order that material be kept confidential; and the AAC may consolidate similar appeals.

N. Effect on Deposit Insurance Assessment Payments

The use of the procedures set forth in these guidelines by an insured institution will not affect, delay, or impede the obligation of that institution to make timely payment of any deposit insurance assessment.

By order of the Board of Directors.

Dated at Washington, DC, this 13th day of April 2010.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2010–8923 Filed 4–16–10; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update Listing of financial institutions in liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as "of record" notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at *http://www.fdic.gov/bank/individual/failed/banklist.html* or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: April 13, 2010. Federal Deposit Insurance Corporation.

Robert Feldman,

Executive Secretary.

Institutions in Liquidation (In alphabetical order)

FDIC ref. no.	Bank Name	City	State	Date closed
10209	Beach First National Bank	Myrtle Beach	SC	4/09/2010

[FR Doc. 2010–8918 Filed 4–16–10; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Issuance of Statement of Federal Financial Accounting Standard 38, Accounting for Federal Oil and Gas Resources

AGENCY: Federal Accounting Standards Advisory Board

ACTION: Notice.

Board Action: Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules of Procedure, as amended in April, 2004, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued Statement of Federal Financial Accounting Standard 38, Accounting for Federal Oil and Gas Resources.

The standard is available on the FASAB home page *http://www.fasab.gov/standards.html.* Copies can be obtained by contacting FASAB at (202) 512–7350.

FOR FURTHER INFORMATION CONTACT: Wendy Payne, Executive Director, at (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: April 14, 2010.

Charles Jackson,

Federal Register Liaison Officer.

[FR Doc. 2010–8966 Filed 4–16–10; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Meeting Schedule for 2011

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Board Action: Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules of Procedure, as amended in April, 2004, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) will meet on the following dates in room 7C13 of the US Government Accountability Office (GAO) Building (441 G St., NW.) unless otherwise noted:

—Wednesday and Thursday, February 23 and 24, 2011

—Wednesday and Thursday, April 27 and 28, 2011

—Wednesday and Thursday, June 22 and 23, 2011

—Wednesday and Thursday, August 24 and 25, 2011

—Wednesday and Thursday, October 26 and 27, 2011

—Monday and Tuesday, December 19 and 20, 2011

The purpose of the meetings are to discuss issues related to:

—FASAB's conceptual framework

—Earmarked Funds

—Property, Plant and Equipment

—Natural Resources

—Deferred Maintenance/Asset Impairment

—Technical Agenda, and

—Any other topics as needed.

Any interested person may attend the meetings as an observer. Board discussion and reviews are open to the public. GAO Building security requires advance notice of your attendance. Please notify FASAB of your planned attendance by calling 202–512–7350 at least one day prior to the respective meeting.

FOR FURTHER INFORMATION CONTACT: Wendy Payne, Executive Director, at (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: April 13, 2010.

Charles Jackson,

Federal Register Liaison Officer.

[FR Doc. 2010–8832 Filed 4–16–10; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 14, 2010.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Hometown Community Bancorp, Inc. Employee Stock Ownership Plan & Trust, and Hometown Community Bancorp, Inc., both in Morton, Illinois; to merge with TSB Financial, Inc., and thereby indirectly acquire Tremont Savings Bank, both in Tremont, Illinois.

Board of Governors of the Federal Reserve System, April 14, 2010.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2010–8950 Filed 4–16–10; 8:45 am]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

[Wildlife Order 187; 4–D–FL–1218]

Public Buildings Service; Key Largo Beacon Annex Site; Key Largo, FL; Transfer of Property

Pursuant to section 2 of Public Law 537, 80th Congress, approved May 19, 1948 (16 U.S.C. 667c), notice is hereby given that:

1. The General Services Administration transferred 4.2 acres of land and improvements, identified as Key Largo Beacon Annex Site, Key Largo, FL to the U.S. Fish and Wildlife Service, Department of the Interior by transfer letter dated August 17, 2004.

2. The above property was conveyed for wildlife conservation in accordance with the provisions of section 1 of Public Law 80–537 (16 U.S.C. 667b), as amended by Public Law 92–432.

FOR FURTHER INFORMATION CONTACT: Mr. Rob Miller, Director of the Real Property Disposal Division (4PZ), by phone on (404) 331–5133.

Dated: April 6, 2010.

Gordon S. Creed,

Acting Deputy Assistant Commissioner, Office of Real Property Utilization & Disposal.

[FR Doc. 2010–8986 Filed 4–16–10; 8:45 am]

BILLING CODE 6820–96–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS), as last amended at 70 FR 48718, dated August 19, 2005, and Chapter AA, Immediate Office of the Secretary, as last amended at 70 FR 48718, dated August 19, 2005, are being amended to establish a new chapter, Chapter AU, "Office of Consumer Information and Insurance Oversight," in the Office of the Secretary. The changes are as follows:

I. Under Part A, Chapter AA, Section AA.10 Organization, insert the

following: "Office of Consumer Information and Insurance Oversight (AU)."

II. Under Part A, establish a new Chapter AU, "Office of Consumer Information and Insurance Oversight" to read as follows:

Chapter AU, Office of Consumer Information and Insurance Oversight

Section AU.00 Mission

Section AU.10 Organization

Section AU.20 Functions

Section AU.00 Mission. The Office of Consumer Information and Insurance Oversight provides leadership for implementing the provisions of the health reform bill that address private health insurance.

Section AU.10 Organization. The Office of Consumer Information and Insurance Oversight is under the direction of a Director, who reports to the Secretary, and consists of the following components:

- Office of the Director (AUA)
- Office of Oversight (AUB)
- Office of Insurance Programs (AUC)
- Office of Consumer Support (AUD)
- Office of Health Insurance Exchanges (AUE)

Section AU.20 Functions.

A. *Office of the Director (AUA).* The Office of the Director is headed by the Director of the Office of Consumer Information and Insurance Oversight, who provides executive direction, leadership, and support to the entire Office. The Director is responsible for carrying out the Office's mission and implementing the functions of the Office of Consumer Information and Insurance Oversight. The Office is comprised of organizational components with responsibilities that include planning, evaluation, regulatory affairs, external relations, and administrative management.

B. *Office of Oversight (AUB).* The Office of Oversight is headed by a Deputy Director, who reports to the Director of the Office of Consumer Information and Insurance Oversight. The Office's responsibilities include: (1) Implementing, monitoring compliance with, and enforcing both the new rules governing the insurance market and the new rules regarding medical loss ratios; (2) performing rate reviews; and (3) issuing rate review grants to states.

C. *Office of Insurance Programs (AUC).* The Office of Insurance Programs is headed by a Deputy Director, who reports to the Director of the Office of Consumer Information and Insurance Oversight. The Office is responsible for administering both the temporary high-risk pool programs and associated funding to states and the early retiree reinsurance program.

D. *Office of Consumer Support (AUD).* The Office of Consumer Support is headed by a Deputy Director, who reports to the Director of the Office of Consumer Information and Insurance Oversight. The Office's responsibilities include: (1) Collecting, compiling and maintaining comparative pricing data for the Department's Web site; (2) providing assistance to enable consumers to obtain maximum benefit from the new health insurance system; and (3) establishing and issuing consumer assistance grants to states.

E. *Office of Health Insurance Exchanges (AUE).* The Office of Health Insurance Exchanges is headed by a Deputy Director, who reports to the Director of the Office of Consumer Information and Insurance Oversight. The Office's responsibilities include: (1) Developing and implementing policies and rules governing state-based exchanges; (2) establishing and issuing planning grants to states; and (3) overseeing the operations of exchanges.

Dated: April 14, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–8949 Filed 4–16–10; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10141, CMS–R–246, CMS–10305 and CMS–10313]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Plan; *Use:* Section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added sections 1860D–1 through D–42 to establish this new program. Part D plans use the information discussed to comply with the eligibility and associated Part D participating requirements. CMS will use this information to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and to ensure that correct information is disclosed to enrollees, both potential enrollees and enrollees. *Form Number:* CMS–10141 (OMB#: 0938–0964); *Frequency:* Yearly; *Affected Public:* Individuals and households, and Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 19,937,660; *Total Annual Responses:* 43,153,271; *Total Annual Hours:* 36,520,101. (For policy questions regarding this collection contact Christine Hinds at 410–786–4578. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Consumer Assessment of Health Care Providers and Systems (CAHPS); *Use:* CMS is required to collect and report information on the quality of health care services and prescription drug coverage available to persons enrolled in a Medicare health or prescription drug plan under provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, the MMA under Sec. 1860D–4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding Medicare prescription drug plans and Medicare Advantage plans and report this information to Medicare beneficiaries prior to the Medicare annual enrollment period. The Medicare CAHPS survey meets the requirement of collecting and publicly reporting consumer satisfaction information. *Form Number:* CMS–R–246 (OMB#: 0938–0732); *Frequency:* Yearly; *Affected Public:* Individuals and households, and Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 567,324; *Total Annual Responses:* 567,324; *Total Annual*

Hours: 242,376. (For policy questions regarding this collection contact Elizabeth Goldstein at 410–786–6665. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Medicare Part C and Part D Data Validation (42 CFR 422.516g and 423.514g); *Use:* Organizations contracted to offer Medicare Part C and Part D benefits are required to report data to the Centers for Medicare & Medicaid Services on a variety of measures. In order for the data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. To meet this goal, CMS is developing reporting standards and data validation specifications with respect to the Part C and Part D reporting requirements. These standards will provide a review process for Medicare Advantage Organizations (MAOs), Cost Plans, and Part D sponsors to use to conduct data validation checks on their reported Part C and Part D data. *Form Number:* CMS–10305 (OMB#: 0938–NEW); *Frequency:* Yearly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 710; *Total Annual Responses:* 710; *Total Annual Hours:* 231,410. (For policy questions regarding this collection contact Terry Lied at 410–786–8973. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* New collection; *Title of Information Collection:* New Quality Measures for Medicare Advantage Organizations; *Use:* For CMS to strengthen the oversight of quality improvement programs implemented by Medicare Advantage organizations, there is a need to collect additional data on quality and outcomes measures in order to better track plan performance. Examples of additional areas on which CMS plans to collect data are post-surgical infections or patient falls. Collection will begin during contract year 2012. The specific data elements that will be collected are currently under development. *Form Number:* CMS–10313 (OMB#: 0938–NEW); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not–for-profit institutions; *Number of Respondents:* 624; *Total Annual Responses:* 624; *Total Annual Hours:* 624,000. (For policy questions regarding this collection contact Sabrina Ahmed at 410–786–7499. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *June 18, 2010:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 13, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–8958 Filed 4–16–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–416 and CMS–R–297]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services Participation Report; *Form Number:* CMS–416 (OMB#: 0938–0354); *Use:* States are required to submit an annual report on the provision of EPSDT services pursuant to section 1902(a)(43)(D) of the Social Security Act. These reports provide CMS with data necessary to assess the effectiveness of State EPSDT programs, to determine a State's results in achieving its participation goal and to respond to inquiries. Respondents are State Medicaid Agencies. The data is due April 1 of every year so States need to have the form and instructions as soon as possible in order to report timely. *Frequency:* Yearly; *Affected Public:* State, Tribal and Local governments; *Number of Respondents:* 56; *Total Annual Responses:* 112; *Total Annual Hours:* 1,568. (For policy questions regarding this collection contact Cindy Ruff at 410–786–5916. For all other issues call 410–786–1326.)

2. 1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Employment Information; *Use:* Section 1837(i) of the Social Security Act provides for a special enrollment period for individuals who delay enrolling in Medicare Part B because they are covered by a group health plan based on their own or a spouse's current employment status. When these individuals apply for Medicare Part B, they must provide proof that the group health plan coverage is (or was) based on current employment status. This form is used by the Social Security Administration to obtain information from employers regarding whether a Medicare beneficiary's coverage under a group health plan is based on current employment status. *Form Number:* CMS–R–297 (OMB#: 0938–0787); *Frequency:* Once; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 5,000; *Total Annual Responses:* 5,000; *Total Annual Hours:* 1,250. (For policy questions regarding this collection contact Kevin

Simpson at 410–786–0017. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by June 18, 2010:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 9, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–8901 Filed 4–16–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: CMS–10295, CMS–10234, CMS–10303, CMS–10066 and CMS–R–193]

Centers for Medicare & Medicaid Services

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Recovery Act—Reporting Requirements for States Under FMAP Increase and TMA Provisions; *Use:* The American Recovery and Reinvestment Act of 2009 (Recovery Act), Public Law 111–5, requires that States submit quarterly reports to the Secretary of Health and Human Services in accordance with section 5001 Temporary Increase of Medicaid Federal Medical Assistance Percentage (FMAP) and section 5004(d) Extension of Transitional Medical Assistance (TMA). The reports under section 5001 are required for the period of October 1, 2008–September 30, 2011. The reports under section 5004 are required beginning on July 1, 2009 until the Federal authority for TMA coverage sunsets (now scheduled to sunset on December 31, 2010). Each State Medicaid agency will submit its quarterly reports to the appropriate Regional Office of CMS. The reports will be compiled and summarized for annual reports to Congress. *Form Number:* CMS–10295 (OMB#: 0938–1073); *Frequency:* Reporting—Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 200; *Total Annual Hours:* 600. (For policy questions regarding this collection contact Richard Strauss at 410–786–2019. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Plan Pre-print implementing Section 6087 of the Deficit Reduction Act: Optional Self-Direction Personal Assistance Services (PAS) Program (Cash and Counseling); *Form Number:* CMS–10234 (OMB#: 0938–1024); *Use:* Information submitted via the State Plan Amendment (SPA) pre-print is used by CMS and Regional Offices to analyze a State's proposal to implement Section 6087 of the Deficit Reduction Act (DRA). State Medicaid Agencies will complete the SPA pre-print, and submit it to CMS for a comprehensive analysis. The pre-print contains assurances, check-off items, and areas for States to describe policies and procedures for subjects such as quality assurance, risk management, and voluntary and involuntary disenrollment; *Frequency:* Reporting—Once; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 20; *Total Annual Hours:* 400. (For policy questions regarding this collection contact Carrie Smith at 410–786–4485. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Medicare Gainsharing Demonstration Evaluation: Physician Focus Groups; *Use:* The proposed physician focus groups are part of an overall evaluation of the Centers for Medicare & Medicaid Services CMS' congressionally mandated Medicare Gainsharing Demonstration Evaluation. The Congress, under Section 5007 of the Deficit Reduction Act (DRA) of 2005, requires CMS to conduct a qualified gainsharing program to test alternative ways that hospitals and physicians can share in efficiency gains. The primary goal of the demonstration is to evaluate gainsharing as a means to align physician and hospital incentives to improve quality and efficiency. The demonstration has two mandated Reports to Congress. Results from physician focus groups will be included in both Reports to Congress. *Form Number:* CMS–10303 (OMB#: 0938–New); *Frequency:* Once; *Affected Public:* Private Sector, Business or other for profits; *Number of Respondents:* 192; *Total Annual Responses:* 96; *Total Annual Hours:* 96. (For policy questions regarding this collection contact William Buczko at 410–786–6593. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Detailed Notice of Discharge (DND); *Use:* A beneficiary/enrollee who wishes to appeal a determination by a Medicare health plan or hospital that inpatient care is no longer necessary, may request Quality Improvement Organization (QIO) review of the determination. On the date the QIO receives the beneficiary's/enrollee's request, it must notify the plan and hospital that the beneficiary/enrollee has filed a request for an expedited determination. The plan (for a managed care enrollee) or hospital (for an original

Medicare beneficiary), in turn, must deliver a detailed notice to the enrollee/beneficiary. *Form Number:* CMS–10066 (OMB#: 0938–1019); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 6,163; *Total Annual Responses:* 13,218; *Total Annual Hours:* 13,218. (For policy questions regarding this collection contact Evelyn Blaemire at 410–786–1803. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Important Message from Medicare (IM); *Use:* Requirements that hospitals notify beneficiaries in inpatient hospital settings of their rights as a hospital patient including their discharge appeal rights are referenced in Section 1866 of the Social Security Act (the Act). The authority for the right to an expedited determination is set forth at Sections 1869 and 1154 of the Act.

The hospital must deliver valid, written notice (the IM) of a patient's rights as a hospital patient including the discharge appeal rights, within 2 calendar days of admission. A follow-up copy of the signed IM is given again as far as possible in advance of discharge, but no more than 2 calendar days before. Follow-up notice is not required if provision of the admission IM falls within 2 calendar days of discharge. The collection has been revised to include documentation of the time when the beneficiary signs the document when it is delivered initially and as a follow-up copy. *Form Number:* CMS–R–193 (OMB#: 0938–1019); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 3,193; *Total Annual Responses:* 13,218; *Total Annual Hours:* 19,680,000. (For policy questions regarding this collection contact Evelyn Blaemire at 410–786–1803. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *May 19, 2010:* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, E-mail: *OIRA_submission@omb.eop.gov.*

Dated: April 9, 2010.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–8900 Filed 4–16–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Confidentiality of Alcohol and Drug Abuse Patient Records—(OMB No. 0930–0092)—Revision

Statute (42 U.S.C. 290dd–2) and regulations (42 CFR part 2) require federally conducted, regulated, or directly or indirectly assisted alcohol and drug abuse programs to keep alcohol and drug abuse patient records confidential. Information requirements are (1) written disclosure to patients about Federal laws and regulations that protect the confidentiality of each patient, and (2) documenting "medical personnel" status of recipients of a disclosure to meet a medical emergency. Annual burden estimates for these requirements are summarized in the table below:

ANNUALIZED BURDEN ESTIMATES

	Annual number of respondents [1]	Responses per respondent	Total responses	Hours per response	Total hour burden
Disclosure					
42 CFR 2.22	10,064	185	1,865,503 [2]	.20	373,101
Recordkeeping					
42 CFR 2.51	10,064	2	20,128	.167	3,361
Total	10,064		1,885,631		376,462

[1] The number of publicly funded alcohol and drug facilities from SAMHSA's 2007 National Survey of Substance Abuse Treatment Services (N–SSATS).

[2] The average number of annual treatment admissions from SAMHSA's 2005–2007 Treatment Episode Data Set (TEDS).

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 12, 2010.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. 2010–8895 Filed 4–16–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Application for Participation in the IHS Scholarship Program

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

Note: The purpose of this second announcement is to provide another opportunity for public comment. The previous **Federal Register** notice was published on December 31, 2009, FR Doc. E9–30947.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires a 30-day advance opportunity for public comment on the proposed information collection project, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the **Federal Register** (74 FR 36714) on July 24, 2009 and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: 0917–0006, "Application for Participation in the IHS Scholarship Program." *Type of Information Collection Request:* Previously Approved Collection (Form changes and additions). *Form Number(s):* IHS–856, 856–2 through 856–24, IHS–815, IHS–816, IHS–817, and IHS–818. Reporting formats are contained in an IHS Scholarship Program application booklet. *Need and Use of Information Collection:* The IHS Scholarship Branch needs this information for program administration and uses the information to solicit, process, and award IHS Pre-graduate, Preparatory, and/or Health Professions Scholarship grants and monitor the academic performance of awardees, to place awardees at payback sites, and for awardees to request additional program information. The IHS Scholarship Program is streamlining the application to reduce the time needed by applicants to complete and provide the information and plans on using information technology to make the application electronically available on the Internet. *Affected Public:* Individuals, not-for-profit institutions and State, local or Tribal Government. *Type of Respondents:* Students pursuing health care professions.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Annual number of responses, Average burden hour per response, and Total annual burden hour(s).

Data collection instrument(s)	Number of respondents	Responses per respondent	Total annual response	Burden hour per response*	Annual burden hours
Scholarship Application (IHS–856)	1,500	1	1,500	1.00 (60 min)	1,500
Application Checklist (IHS–856–2)	1,500	1	1500	0.13 (8 min)	200
Faculty/Employer Evaluation (IHS–856–3)	1,500	2	3,000	0.83 (50 min)	2,500
Narrative Statements (IHS–856–4)	1,500	1	1,500	0.75 (45 min)	1,125
Delinquent Federal Debt (IHS–856–5)	1,500	1	1,500	0.13 (8 min)	200
Course Curriculum Verification (IHS–856–6)	1,500	1	1,500	0.70 (42 min)	1,050
Verification of Acceptance (IHS–856–7)	400	1	400	0.13 (8 min)	53
Recipient's Initial Program Progress Report (IHS–856–8).	400	1	400	0.13 (8 min)	53
Notification of Academic Problem (IHS–856–9)	50	1	50	0.13 (8 min)	7
Change of Status (IHS–856–10)	50	1	50	0.45 (25 min)	21
Request for Approval of Deferment (IHS–856–11).	50	1	50	0.13 (8 min)	7
Preferred Placement (IHS–856–12)	200	1	200	0.75 (45 min)	150
Notice of Impending Graduation (IHS–856–13)	200	1	200	0.17 (10 min)	33
Notification of Deferment Program (IHS–856–14)	50	1	50	0.13 (8 min)	7
Placement Update (IHS–856–15)	200	1	200	0.18 (11 min)	37
Annual Status Report (IHS–856–16)	200	1	200	0.25 (15 min)	50
Extern Site Preference Request (IHS–856–17)	125	1	125	0.13 (8 min)	17
Request for Extern Travel Reimbursement (IHS–856–18).	125	1	125	0.10 (6 min)	13
Lost Stipend Checks (IHS–856–19)	50	1	50	0.13 (8 min)	7
Request for Tutorial Assistance (IHS–856–20)	150	1	150	0.13 (8 min)	20
Summer School Request (IHS–856–21)	75	1	75	0.10 (6 min)	8
Change of Name or Address (IHS–856–22)	50	1	50	0.13 (8 min)	7
Request for Credit Validation (IHS–856–23)	30	1	30	0.10 (6 min)	3
Faculty/Advisor Evaluation (IHS–856–24)	1,500	2	3,000	0.83 (50 min)	2,500
Acknowledgment Card (IHS–815)	1,500	1	1,500	0.03 (2 min)	50
Address Change Notice (IHS–816)	50	1	50	0.02 (1 min)	1
Scholarship Program Agreement (IHS–817)	175	1	175	0.05 (3 min)	9
Health Professions Contract (IHS–818)	225	1	225	0.05 (3 min)	11
Total			17,855		9,639

* For ease of understanding, burden hours are also provided in actual minutes.

There is no direct cost to respondents other than their time to voluntarily complete the forms and submit them for consideration. The estimated cost in time to respondents, as a group, is $99,355.00 (9639 burden hours × 2009 GS–3 base pay rate = $10.31 per burden hour). This total dollar amount is based upon the number of burden hours per

data collection instrument, rounded to the nearest dollar.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimates are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, *Attention:* Desk Officer for IHS, New Executive Office Building, Room 10235, Washington, DC 20503.

Send Comments and Requests for Further Information: To request more information on the proposed collection or to obtain a copy of the data collection instrument(s) and/or instruction(s) contact: Mr. Hershel Gorham, IHS Reports Clearance Officer, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852, call non-toll free (301) 443–5932; send via facsimile to (301) 443–9879; or send your e-mail requests, comments, and return address to: *hershel.gorham@ihs.gov.*

Comment Due Date: Comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: April 8, 2010.

Yvette Roubideaux,

Deputy Director, Indian Health Service.

[FR Doc. 2010–8842 Filed 4–16–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Assay Systems for Drug Efficacy in Cancer Stem Cells.

Date: April 28, 2010.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Room 6006, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Kirt Vener, PhD, Branch Chief, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8061, Bethesda, MD 20892–8329, 301–496–7174, *venerk@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel, Breast Cancer Biology.

Date: May 20, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Zhiqiang Zou, MD, PhD, Scientific Review Officer, National Cancer Institute, National Institutes of Health, 6116 Executive Blvd., Room 8050A, MSC 8329, Bethesda, MD 20852, *zouzhiq@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel, Molecular Oncology—Basic, Translational and Clinical Studies.

Date: May 25–26, 2010

Time: 7:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: David G. Ransom, PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 8133, Bethesda, MD 20892–8328, 301–451–4757, *david.ransom@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 10, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–8984 Filed 4–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 materials, 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 Neurological Disorders and Stroke Special Emphasis Panel; NINDS Conference Grant Review Panel.

Date: April 19, 2010.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Virtual Meeting).

Contact Person: Alan L. Willard, PhD, Chief, Scientific Review Branch, NINDS/NIH/DHHS, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–5390, *willarda@ninds.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to timing limitations imposed by the review funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the

Neurosciences, National Institutes of Health, HHS)

Dated: April 7, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–8973 Filed 4–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 individualsassociated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; R21 Exploratory Research Grant Award.

Date: May 5, 2010.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS, Keystone Building, 530 Davis Drive, 2128, Research Triangle, NC 27709, (Telephone Conference Call)

Contact Person: Leroy Worth, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (919) 541–0670, *worth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: April 9, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–8969 Filed 4–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2010–0030]

Homeland Security Advisory Council

AGENCY: The Office of Policy, DHS.

ACTION: Notice of Open Teleconference Federal Advisory Committee Meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will meet via teleconference for the purpose of reviewing the findings and recommendations of the HSAC's Countering Violent Extremism Working Group.

DATES: The HSAC conference call will take place from 4 p.m. to 5 p.m. EST on Thursday, May 13, 2010. Please be advised that the meeting is scheduled for one hour and all participating members of the public should promptly call-in at the beginning of the teleconference.

ADDRESSES: The HSAC meeting will be held via teleconference. Members of the public interested in participating in this teleconference meeting may do so by following the process outlined below (*see* "Public Attendance").

Written comments must be submitted and received by May 7, 2010. Comments must be identified by Docket No. DHS–2010–0030 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: HSAC@dhs.gov.* Include docket number in the subject line of the message.
- *Fax:* (202) 282–9207
- *Mail:* Homeland Security Advisory Council, Department of Homeland Security, Mailstop 0850, 245 Murray Lane, SW., Washington, DC 20528.

Instructions: All submissions received must include the words "Department of Homeland Security" and DHS–2010–0030, the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the DHS Homeland Security Advisory Council, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: HSAC Staff at *hsac@dhs.gov* or 202–447–3135.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2. The HSAC provides independent advice to the Secretary of the Department of Homeland Security to aid in the creation and implementation of critical and actionable policies and capabilities across the spectrum of homeland security operations. The HSAC periodically reports, as requested, to the Secretary, on such matters. The Federal Advisory Committee Act requires Federal Register publication 15 days prior to a meeting. The HSAC will meet to review the Countering Violent Extremism Working Group findings and recommendations.

Public Participation: Members of the public may register to participate in this HSAC teleconference via afore mentioned procedures. Each individual must provide his or her full legal name, e-mail address and phone number no later than 5 p.m. EST on May 11, 2010, to a staff member of the HSAC via e-mail at *HSAC@dhs.gov* or via phone at (202) 447–3135. HSAC conference call details will be provided to interested members of the public at this time.

Information on Services for Individuals with Disabilities: For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact the HSAC as soon as possible.

Dated: *April 13th, 2010.*

Mike Miron,

Director, Homeland Security Advisory Council, DHS.

[FR Doc. 2010–8953 Filed 4–16–10; 8:45 am]

BILLING CODE 9110–9M–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2010–0187]

Certificate of Alternative Compliance for the Offshore Supply Vessel LEBOUEF TIDE

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the offshore supply vessel LEBOUEF TIDE as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternate Compliance was issued on March 4, 2010.

ADDRESSES: The docket for this notice is available for inspection or copying at 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. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2010–0187 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call LTJG Christine Dimitroff, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504–671–2176. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

A Certificate of Alternative Compliance, as allowed under title 33, Code of Federal Regulation, parts 81 and 89, has been issued for the offshore supply vessel LEBOUEF TIDE. The horizontal distance between the forward and aft masthead lights may be 25′–9″. Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I, paragraph 3(a) of the 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act, would result in an aft masthead light location directly over the cargo deck where it would interfere with loading and unloading operations.

The Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c), and 33 CFR 81.18.

Dated: March 26, 2010.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, By Direction of the Commander, Eighth Coast Guard District.

[FR Doc. 2010–8862 Filed 4–16–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2010–0186]

Certificate of Alternative Compliance for the Offshore Supply Vessel RIG RUNNER

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the offshore supply vessel RIG RUNNER as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternative Compliance was issued on March 8, 2010.

ADDRESSES: The docket for this notice is available for inspection or copying at 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. You may also find this docket on the Internet by going to *http://www.regulations.gov,* selecting the Advanced Docket Search option on the right side of the screen, inserting USCG–2010–0186 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504–671–2153. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

A Certificate of Alternative Compliance, as allowed under title 33, Code of Federal Regulations, parts 81 and 89, has been issued for the offshore supply vessel RIG RUNNER, O.N. 1222591. Full compliance with 72 COLREGS and Inland Rules Act would hinder the vessel's ability to maneuver within close proximity of offshore platforms. The forward masthead light may be located on the top forward portion of the pilothouse 17′ above the hull. Placing the forward masthead light at the height as required by Annex I, paragraph 2(a) of the 72 COLREGS would result in a masthead light location highly susceptible to damage when working in close proximity to offshore platforms. Furthermore the horizontal distance between the forward and aft masthead lights may be 14.1′. Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I, paragraph 3(a) of the 72 COLREGS and Annex I, Section 84.05(a) of the Inland Rules Act would result in an aft masthead light location directly over the aft cargo deck where it would interfere with loading and unloading operations.

A Certificate of Alternative Compliance, as allowed under title 33, Code of Federal Regulations, parts 81 and 89, has been issued for the offshore supply vessel RIG RUNNER, O.N. 1222591. The Certificate of Alternative Compliance allows for the vertical placement of the forward masthead light to deviate from requirements set forth in Annex I, paragraph 2(a) of 72 COLREGS. In addition the Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS and Annex I, Section 84.05(a) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c), and 33 CFR 81.18.

Dated: March 26, 2010.

J.W. Johnson,

Commander, U.S. Coast Guard, Chief, Inspections and Investigations Branch, By Direction of the Commander, Eighth Coast Guard District.

[FR Doc. 2010–8858 Filed 4–16–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2010–0276]

Commercial Fishing Industry Vessel Safety Advisory Committee; Meeting

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Commercial Fishing Industry Vessel Safety Advisory Committee (CFIVSAC) will meet in Oakland, CA, to discuss various issues relating to commercial vessel safety in the fishing industry. This meeting will be open to the public.

DATES: The Committee will meet on May 11–13, 2010, from 8 a.m. to 5 p.m. each day. This meeting may close early if all business is finished.

Written material and requests to make oral presentations should reach the Coast Guard on or before April 23, 2010. Requests to have a copy of your material distributed to each member of the committee should also reach the Coast Guard on or before April 23, 2010.

ADDRESSES: The Committee will meet at the Waterfront Hotel, 10 Washington Street, Oakland, CA 94607. (510–836–3800, *http://www.waterfronthoteloakland.com.*)

Send written material and requests to make oral presentations via mail to Captain Eric P. Christensen, Designated Federal Officer (DFO) of CFIVSAC, United States Coast Guard, Office of Vessel Activities (CG–543), 2100 2nd Street, SW., Washington, DC 20593–7581. This notice and documents identified in the Supplementary Information section as being available in the docket may be viewed in our online docket, USCG–2010–0276, at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Jack Kemerer, Assistant to the DFO of CFIVSAC, by telephone at 202–372–1249, fax 202–372–1917, *e-mail: Jack.A.Kemerer@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463).

Agenda of Meeting

The agenda for the CFIVSAC meeting is as follows:

(1) Introductions and comments.

(2) Updates on Coast Guard Commercial Fishing Vessel Safety activities, pending legislation affecting commercial fishing vessels, and status report on the Commercial Fishing Vessel Safety Rulemaking.

(3) Commercial Fishing Vessel Safety District Coordinator reports.

(4) Industry updates.

(5) Report of ongoing research work and safety related projects by the National Institute for Occupational Safety and Health (NIOSH).

(6) Comments from the public.

(7) Discussions and working group sessions by the Communications and Risk Management Subcommittees, and others that may be established, on current program strategies, future plans, recommendations to the Coast Guard, and goals for CFIVSAC.

Procedural

The CFIVSAC meeting is open to the public. Please note that from 8–9 a.m. on the first day of the meeting, May 11, 2010, the committee members will meet to discuss administrative matters, including member training. This one-hour meeting on administrative matters is for committee members only in accordance with 41 CFR 102.3–160; the CFIVSAC meeting will commence at 9 a.m. on May 11, 2010. Please note, also, the meeting may close early if all business is finished.

At the Chair's discretion, members of the public may make presentations during the meeting. If you would like to make an oral presentation at the meeting, please send a request to the DFO no later than April 23, 2010. Written material for distribution at the meeting should reach the DFO no later than April 23, 2010. If you would like a copy of your material distributed to each member of the committee in advance of the meeting, please submit 20 copies to the DFO no later than April 23, 2010. All requests and materials must be sent via mail as described in **ADDRESSES**.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact the DFO as soon as possible, but no later than April 30, 2010.

Dated: April 12, 2010.

J.G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2010–8857 Filed 4–16–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Quarterly IRS Interest Rates Used in Calculating Interest on Overdue Accounts and Refunds on Customs Duties

AGENCY: Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This notice advises the public of the quarterly Internal Revenue Service interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties. For the calendar quarter beginning April 1, 2010, the interest rates for overpayments will be 3 percent for corporations and 4 percent for non-corporations, and the interest rate for underpayments will be 4 percent. This notice is published for the convenience of the importing public and Customs and Border Protection personnel.

DATES: *Effective Date:* April 1, 2010.

FOR FURTHER INFORMATION CONTACT: Ron Wyman, Revenue Division, Collection and Refunds Branch, 6650 Telecom Drive, Suite #100, Indianapolis, Indiana 46278; telephone (317) 614–4516.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85–93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of customs duties must be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621 and 6622. Section 6621 was amended (at paragraph (a)(1)(B) by the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105–206, 112 Stat. 685) to provide different interest rates applicable to overpayments: one for corporations and one for non-corporations.

The interest rates are based on the Federal short-term rate and determined by the Internal Revenue Service (IRS) on behalf of the Secretary of the Treasury on a quarterly basis. The rates effective for a quarter are determined during the first-month period of the previous quarter.

In Revenue Ruling 2010–9, the IRS determined the rates of interest for the calendar quarter beginning April 1, 2010, and ending on June 30, 2010. The interest rate paid to the Treasury for underpayments will be the Federal short-term rate (1%) plus three percentage points (3) for a total of four percent (4). For corporate overpayments, the rate is the Federal short-term rate (1%) plus two percentage points (2) for a total of three percent (3). For overpayments made by non-corporations, the rate is the Federal short-term rate (1%) plus three percentage points (3) for a total of four percent (4). These interest rates are subject to change for the calendar quarter beginning July 1, 2010, and ending September 30, 2010.

For the convenience of the importing public and Customs and Border Protection personnel the following list of IRS interest rates used, covering the period from before July of 1974 to date, to calculate interest on overdue accounts and refunds of customs duties, is published in summary format.

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate over-payments (Eff. 1–1–99) (percent)
070174	063075	6	6	
070175	013176	9	9	
020176	013178	7	7	
020178	013180	6	6	
020180	013182	12	12	
020182	123182	20	20	
010183	063083	16	16	
070183	123184	11	11	
010185	063085	13	13	
070185	123185	11	11	
010186	063086	10	10	
070186	123186	9	9	
010187	093087	9	8	
100187	123187	10	9	
010188	033188	11	10	
040188	093088	10	9	
100188	033189	11	10	
040189	093089	12	11	
100189	033191	11	10	
040191	123191	10	9	
010192	033192	9	8	
040192	093092	8	7	
100192	063094	7	6	
070194	093094	8	7	
100194	033195	9	8	
040195	063095	10	9	
070195	033196	9	8	
040196	063096	8	7	
070196	033198	9	8	
040198	123198	8	7	
010199	033199	7	7	6
040199	033100	8	8	7
040100	033101	9	9	8
040101	063001	8	8	7
070101	123101	7	7	6
010102	123102	6	6	5
010103	093003	5	5	4
100103	033104	4	4	3
040104	063004	5	5	4
070104	093004	4	4	3
100104	033105	5	5	4
040105	093005	6	6	5
100105	063006	7	7	6
070106	123107	8	8	7
010108	033108	7	7	6
040108	063008	6	6	5
070108	093008	5	5	4
100108	123108	6	6	5
010109	033109	5	5	4
040109	063010	4	4	3

Dated: April 13, 2010.

Alan Bersin,

Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2010–8961 Filed 4–16–10; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

National Park Service

60-Day Notice of Intention To Request Clearance of Collection of Information—Opportunity for Public Comment

AGENCY: National Park Service, Interior.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3507) and 5 CFR 1320, Reporting and Recordkeeping Requirements, the National Park Service invites public comments on an extension of a currently approved collection of information Office of Management and Budget (OMB) #1024–0047. 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.

DATES: Public comments will be accepted on or before June 18, 2010.

ADDRESSES: Send comments to Michael D. Wilson, Chief or Laurie Heupel,

Outdoor Recreation Planner, State and Local Assistance Programs Division, National Park Service (2225), 1849 C Street, NW., Washington, DC 20240–0001 or via e-mail at *michael_d_wilson@nps.gov* or *laurie_heupel@nps.gov.* All responses to this notice will be summarized and included in the request.

To Request a Draft of Proposed Collection of Information Contact: Michael D. Wilson, Chief or Laurie Heupel, Outdoor Recreation Planner, State and Local Assistance Programs Division, National Park Service (2225), 1849 C Street, NW., Washington, DC 20240–0001 or via e-mail at *Michael_d_wilson@nps.gov* or *Laurie_heupel@nps.gov.* You are entitled to a copy of the entire ICR package free-of-charge.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1024–0047.

Title: Land and Water Conservation Fund (LWCF) Conversions of Use Provisions.

Form: None.

Type of Request: Extension of currently approved information collection.

Expiration Date: August 31, 2010.

Abstract: In order to convert sites and facilities assisted under the LWCF to other than public outdoor recreation uses, the grant recipient must submit documentation for NPS consideration. Documentation includes appraisal reports, statements regarding need for the conversion, and such additional information as may be necessary given the peculiar nature of the specific request.

Affected Public: State Governments, DC and Territories.

Obligation to Respond: Required to Obtain a Benefit.

Frequency of Response: On occasion.

Estimated total annual responses: 450.

Estimated average completion time per response: 1 hour.

Estimated annual reporting burden: 450 hours.

Estimated annual non hour cost burden: $9,560.

The NPS also is asking for comments on (1) the practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. 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 we cannot guarantee that we will be able to do so.

Dated: April 14, 2010.

Cartina Miller,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2010–8978 Filed 4–16–10; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF INTERIOR

National Park Service

60-Day Notice of Intention to Request Clearance of Collection of Information; Opportunity for Public Comment

AGENCY: National Park Service, Interior.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 and 5 CFR part 1320, Reporting and Record Keeping Requirements, the National Park Service (NPS) invites public comments on an extension of a currently approved collection of information Office of Management and Budget (OMB) #1024–0021. 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.

DATES: Public comments on this Information Collection Request (ICR) will be accepted on or before June 18, 2010.

ADDRESSES: Send comments directly to: Ms. Robbin Owen, Chief, National Park Service, National Capital Region, National Mall and Memorial Parks, Division of Park Programs, 1100 Ohio Drive, SW., Room 128, Washington, DC 20242; or via fax at 202–401–2430; or via e-mail at *Robbin_Owen@nps.gov.* All responses to the notice will be summarized and included in the request for the OMB approval. All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: *To Request a Draft of Proposed Collection of Information Contact:* Ms. Robbin Owen, Chief, NPS, National Capital Region, National Mall and Memorial Parks, Division of Park Programs, 1100 Ohio Drive, SW., Room 128, Washington, DC 20242; or via phone at 202- 619–7225; or via fax at 202–401–2430; or via e-mail at *Robbin_Owen@nps.gov.* You are entitled to a copy of the entire ICR package free of charge once the package is submitted to OMB for review. You can access this ICR at *http://www.reginfo.gov/public/.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1024–0021.

Title: National Park Service, National Capital Region Application for a Permit to Conduct a Demonstration or Special Event in Park Areas and a Waiver of Numerical Limitations on Demonstrations for White House Sidewalk and/or Lafayette Park.

Form(s): None.

Expiration Date: 11/30/2010.

Type of Request: Extension of a currently approved collection of information.

Abstract: The NPS requests comments on an application form that allows the Park Programs Division of National Mall and Memorial Parks to process requests from individual and organizations to hold public gatherings on NPS property. These public gatherings consist of special events and demonstrations that the NPS is charged with regulating to insure protection of cultural and natural resources within NPS property. The NPS will use the information you submit to determine whether or not to make modifications to the application form. Once the NPS makes any modifications that it may decide to adopt, the NPS plans to submit a proposed collection of information package to OMB with a request that OMB approve the package and reinstate the OMB clearance number. The information collection responds to the statutory requirements that the NPS preserve park resources and regulate the use of units of the National Park System. The information to be collected identifies: (1) Those individuals and/or organizations that wish to conduct a public gathering on NPS property in the National Capital Region, (2) the logistics of a proposed demonstration or special event that aid the NPS in regulation activities to insure that they are consistent with the NPS mission, (3) potential civil disobedience and traffic control issues for the assignment of United States Park Police personnel, (4) circumstances which may warrant to be assigned to the event for the purpose of covering potential cost to repair damage caused by the event. You may obtain copies of the application from the source listed below (see the "send comments to" section) *http://www.nps.gov/nama/planyourvisit/permits.htm.*

Description of respondents: Respondents are those individuals or organizations that wish to conduct a

special event or demonstration on NPS properties with the National Capital Region that lie within the geographical limits set forth in 36 CFR 7.96(a).

Obligation to Respond: Required to Obtain a Benefit.

Frequency of Response: On occasion.

Estimated average number of responses: 2,051 per year.

Estimated average time burden per respondent: .5 hours.

Estimated total annual reporting burden: 1,026 hours.

Estimated annual non hour cost burden: $102,550.

Comments are invited on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. 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: April 12, 2010.

Cartina A. Miller,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2010–8983 Filed 4–16–10; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CACA 49537, LLCAD08000, L51030000.ER0000, LVRAB109AA02]

Notice of Availability of the Draft Environmental Impact Statement/Staff Assessment and Possible Amendment to the California Desert Conservation Area Plan for the Calico Solar (Formerly SES Solar One) Project, San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Department of the Interior (DOI), Bureau of Land Management (BLM) and the California Energy Commission (CEC) have jointly released a Draft Environmental Impact Statement (EIS)/Staff Assessment (SA), including a possible Draft Amendment to the California Desert Conservation Area (CDCA) Plan (1980, as amended), for the Calico Solar (formerly Stirling Energy Systems Solar One) Project, San Bernardino County, California. The Draft EIS/SA, prepared in compliance with the National Environmental Policy Act of 1969, as amended (NEPA), the Federal Land Policy and Management Act of 1976, as amended (FLPMA), and the California Environmental Quality Act (CEQA), evaluates the environmental impacts of constructing and operating an 850 megawatt (MW) solar power facility on 8,230 acres of BLM-administered land. The Draft EIS/SA is jointly prepared by the BLM and the CEC in response to Calico Solar, LLC's right-of-way (ROW) application to the BLM and its Application for Certification (AFC) to the CEC.

DATES: The publication of the EPA's Notice of Availability of this Draft EIS in the **Federal Register** initiates a 90-day public comment period. To ensure that comments will be considered, the BLM must receive written comments on the Draft EIS/SA and plan amendment within 90 days following the date the EPA publishes its Notice of Availability in the **Federal Register.** The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: Copies of the Calico Solar Project Draft EIS/SA are available from the BLM Barstow Field Office, 2601 Barstow Road, Barstow, California 92311. The document may also be viewed at public libraries in San Bernardino County, Sacramento, Fresno, San Francisco, Los Angeles, Eureka, and San Diego, California.

FOR FURTHER INFORMATION CONTACT: Jim Stobaugh, BLM Project Manager, by mail: P.O. Box 12000, Reno, Nevada 89520; phone: (775) 861–6478; or e-mail: *Jim_Stobaugh@blm.gov.*

SUPPLEMENTARY INFORMATION: On March 14, 2007, SES Solar Six, LLC and SES Solar Three, LLC submitted applications for ROW grants to the BLM to construct and operate a concentrated solar dish power plant facility on Federal public lands in San Bernardino County, California. The two ROW application areas were subsequently combined into one project (SES Solar One) proposed for an 8,230-acre site located immediately north of Interstate 40, approximately 37 miles east of Barstow, California. On December 2, 2008, SES Solar One, LLC (SES Solar Three, LLC and SES Solar Six, LLC) submitted an AFC to the CEC to construct and operate the SES Solar One Project. In January 2010, the project name was formally changed to Calico Solar as a result of SES Solar Three, LLC merging with SES Solar Six, LLC to create Calico Solar, LLC.

The proposed action is to construct an 850-MW, 8,230-acre (13 square mile) solar energy facility on BLM-administered land. Approximately 1,718 acres of public land within the proposed project area were either donated to the BLM or acquired by the BLM with Land and Water Conservation Funds (LWCF). The project proposal includes building about 34,000, 25-kilowatt Stirling solar dish systems. Each solar dish system consists of an approximately 38-foot high by 40-foot wide solar concentrator dish that supports an array of curved glass mirrors. These mirrors would automatically track the sun and focus solar energy onto a power conversion unit that generates electricity.

The Calico Solar Project would also include a number of related facilities and infrastructure, including:

- A new 230-kilovolt (kV) Calico Substation; approximately 2 miles of single-circuit 230-kV transmission line to connect the new Calico Substation to the existing Southern California Edison (SCE) Pisgah Substation;
- Project roads and fencing;
- An administration building; and
- A 45,000 square foot main services complex.

Approximately 739 feet of the new 230-kV transmission line would be outside of the project area. The solar facility would operate for about 20 years based on the Purchase Power Agreement signed with SCE on August 9, 2005. Upgrades to the SCE transmission system are needed to transmit the electricity generated from the Calico Solar Project. These upgrades would take place outside the Calico Solar project area.

The BLM is considering amending the CDCA Plan as part of the proposed action. The CDCA Plan requires that all sites associated with power generation or transmission not identified in the CDCA Plan be considered through the BLM land use planning amendment process. If the BLM decides to approve the ROW grant, the BLM would also amend the CDCA Plan, as required. The BLM's proposed action in the Draft EIS/SA is to authorize the 850-MW Calico Solar Project and approve the CDCA Plan amendment in response to the application received from Calico Solar, LLC.

The action alternatives include: (1) The proposed action (as described above); (2) a 720-MW, 6,512-acre (10.2

square mile) alternative which avoids the 1,718 acres of donated and LWCF-acquired lands; and (3) a reduced acreage alternative (2,320 acres (3.6 square mile)) which would connect a proposed 275-MW transmission upgrade to the SCE grid capacity. As required under CEQA and NEPA, the EIS is also analyzing the following three "no action" alternatives: (1) Deny the Calico Solar Project applications and not amend the CDCA Plan; (2) deny the Calico Solar Project but amend the CDCA Plan to allow other solar energy projects on the proposed project site; and (3) deny the Project and amend the CDCA Plan to prohibit solar energy projects on the proposed project site. As part of its review of the Calico Solar, LLC applications, the BLM will consider the Energy Policy Act of 2005, Secretarial Order 3283 *Enhancing Renewable Energy Development on the Public Lands,* and Secretarial Order 3285 *Renewable Energy Development by the Department of the Interior.*

If the Calico Solar Project is approved and constructed, a number of related future actions are also anticipated. The NEPA and CEQA require examination of reasonably foreseeable actions resulting from a project under consideration. Accordingly, the Draft EIS/SA examines the construction and operational impacts of future SCE transmission substation/transmission line upgrade options and the nature and scope of the probable impacts of each scenario, should they occur as a result of the approval of the Calico Solar Project. These future scenarios would require additional utility and ROW applications from SCE and additional environmental review under CEQA and NEPA.

The BLM's purpose and need for the Calico Solar project is to respond to the Calico Solar, LLC's application for a ROW grant to construct, operate, and decommission a solar thermal facility on public lands in compliance with Title V of FLPMA (43 U.S.C. 1761), the BLM's ROW regulations, and other applicable Federal laws. Upon completion and consideration of the Final EIS/SA, the BLM will decide whether to approve, approve with modification, or deny issuance of a ROW grant to Calico Solar, LLC for the proposed Calico Solar Project.

A joint Federal-State environmental review of the Calico Solar Project is being prepared as a result of a 2007 Memorandum of Understanding (MOU) between the California Desert District of the BLM and the CEC to conduct joint environmental review of solar thermal projects that are proposed on Federal land managed by the BLM in California. The MOU assigns the CEC as the lead agency for preparing the environmental documents. The joint environmental review is being conducted in a single combined NEPA/CEQA analysis process and document. The Draft EIS/SA analyzes site-specific impacts of the proposed project on air quality; biological, cultural, water, soil, visual, paleontological, and geologic resources; recreation; land use; noise; public health; socioeconomics; and traffic and transportation. The Draft EIS/SA also addresses hazardous materials handling, waste management, worker safety, fire protection, facility design engineering, transmission system engineering, transmission line safety, and nuisance.

Additionally, the applicant has applied to the Department of Energy (DOE) for a loan guarantee under Title XVII of the Energy Policy Act of 2005, as amended by Section 406 of the American Recovery and Reinvestment Act of 2009, Public Law 111–5. Should the DOE decide to enter into negotiation of a possible loan guarantee with the Applicant, the DOE would become a cooperating agency in developing the Final EIS. The purpose and need for action by the DOE would be to comply with its mandate under the Energy Policy Act of 2005 to select eligible projects that meet the goals of the Act.

A Notice of Intent to Prepare an EIS/SA and Land Use Plan Amendment for the SES Solar One Project (now called Calico Solar), San Bernardino County, California was published in the **Federal Register** on June 8, 2009 (73 FR 27176). The BLM held a public scoping meeting in Barstow, California, on June 22, 2009. The formal 30-day public scoping period ended July 7, 2009.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 1506.10 and 43 CFR 1610.2.

Tom Pogacnik,

Deputy State Director.

[FR Doc. 2010–8910 Filed 4–16–10; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZP02000–10–L51010000.FX0000.LVRWA09A2400; AZA 034187]

Notice of Availability of the Draft Environmental Impact Statement for the Proposed Sonoran Solar Energy Project, Maricopa County, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), the Bureau of Land Management (BLM) has prepared a Draft Environmental Impact Statement (EIS) for the proposed Sonoran Solar Energy Project (SSEP) and by this notice is announcing the opening of the comment period.

DATES: To ensure comments will be considered, the BLM must receive written comments on the SSEP Draft EIS within 45 days following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register.** The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: You may submit comments related to the Proposed Sonoran Solar Energy Project by any of the following methods:

- *E-mail: sonoransolar@blm.gov*; or
- *Mail:* BLM Phoenix District Office, Lower Sonoran Field Office, Sonoran Solar Energy Project, Attention: Joe Incardine, National Project Manager, 21605 North 7th Avenue, Phoenix, Arizona 85027.

Copies of the Proposed Sonoran Solar Energy Project Draft EIS are available in the Lower Sonoran Field Office at the above address.

The document may also be viewed at public libraries in Maricopa County, Arizona:

- Buckeye Public Library, 310 N. 6th Street, Buckeye, Arizona 85236.
- Gila Bend Public Library, 202 N. Euclid Avenue, Gila Bend, Arizona 85337.
- Goodyear Public Library, 250 N. Litchfield Road, Goodyear, Arizona 85338.

You may also access the document on the Internet at: *http://www.blm.gov/az/st/en/prog/energy/solar/sonoran_solar.html.*

FOR FURTHER INFORMATION CONTACT: Joe Incardine, BLM National Project

Manager, telephone: 801–524–3833; address: BLM Phoenix District Office, Lower Sonoran Field Office, 21605 North 7th Avenue, Phoenix, Arizona 85027; e-mail: *Joe_Incardine@blm.gov.*

SUPPLEMENTARY INFORMATION: The Draft EIS was prepared by the BLM in response to Boulevard Associates, LLC's (Boulevard) right-of-way (ROW) application to the BLM. Boulevard is proposing to construct up to a 375 megawatt (MW) concentrated solar thermal (CST) power plant and ancillary facilities on approximately 3,688 acres (5.76 square miles) on BLM-administered land. The proposed project area totals approximately 3,702 acres and also includes land owned by the Arizona State Land Department (approximately 5.3 acres) and private land owners (approximately 9.4 acres). The proposed CST project would be sited in the Little Rainbow Valley, east of State Route 85 and south of the Buckeye Hills in Maricopa County, Arizona. The CST project is in the BLM's Lower Gila South Planning Area and would be managed in accordance with the Lower Gila South Resource Management Plan (1988) (RMP), as amended (2005). Related facilities include road construction and improvements, a gas pipeline, electric lines, and a water well field and pipeline. Boulevard's ROW application only applies to BLM-administered land.

The BLM completed a land use plan conformance analysis of the SSEP and determined that the proposed land use is in conformance with the Lower Gila South RMP, as amended. As part of its review of the Boulevard's ROW application, the BLM will consider the Energy Policy Act of 2005, and Secretarial Orders 3283 *Enhancing Renewable Energy Development on the Public Lands* and 3285 *Renewable Energy Development by the Department of the Interior.*

The proposed SSEP would consist of two independent, concentrated solar electric generating facilities with expected outputs of 125 MW and 250 MW. Both facilities would use parabolic trough solar thermal technology to produce electrical power using steam turbine generators fed from solar steam generators. The generators would connect to a new SSEP 500-kilovolt onsite switchyard. Electricity from the new switchyard would be transmitted through a generation tie-line to connect to the existing Jojoba Substation. The proposed SSEP would use a wet-cooling tower for power plant cooling with up to 3,003 acre-feet per year of water being supplied from an onsite groundwater well field. Three natural gas co-firing boilers would be constructed to augment solar heating when less than optimal solar conditions existed (night time, cloud cover, etc.), and would provide up to 25 percent of annual total electric production. The boilers would be supplied with natural gas via a new 5-mile, 8-inch pipeline. A thermal energy storage (TES) system may also be installed to supplement electrical output during reduced solar activity or to extend electrical output into the evening hours. The TES would use molten salt as its energy storage medium.

The proposed SSEP would include a number of related facilities and infrastructure, including power blocks and solar trough arrays (2,300 acres), evaporation ponds, access roads, administration buildings and other support facilities, a land treatment unit, drainage collection and discharge facilities, and open areas totaling 1,400 acres for a total footprint of about 3,700 acres.

As required under NEPA, the EIS also analyzes a no action alternative which would preclude development of the SSEP in any configuration and maintain existing land uses in the project area. The three action alternatives include: (1) The proposed action (as described above); (2) Alternative A: Reduced Water Use (using a dry-cooling technology); and (3) Alternative B: Reduced Footprint (a 250 MW wet-cooled facility occupying 2,320 acres). Alternatives A and B were developed in response to issues raised during the scoping process. A Brine Concentrator Option is also analyzed as a component of the proposed action and Alternative B.

The BLM's purpose and need for the Sonoran Solar Energy Project is to respond to Boulevard's application for a ROW grant to construct, operate, and decommission a solar thermal facility on public lands in compliance with Title V of the Federal Land Policy Management Act (43 U.S.C. 1761), the BLM's ROW regulations, and other applicable Federal laws. Upon completion and consideration of the Final EIS, the BLM will decide whether to approve, approve with modification, or deny issuance of a ROW grant to Boulevard for the proposed Sonoran Solar Energy Project. If approved, the solar facility would be authorized by the BLM for a period of 30 years.

The Draft EIS analyzes the anticipated effects of the proposed SSEP and alternatives on air quality, noise, geology and minerals, soils, surface and ground water resources, vegetation and special-status species, wildlife and special-status species, cultural resources, paleontology (fossils), land use and access, livestock grazing, recreation, wilderness characteristics, visual resources, social and economic conditions, special designation areas, transportation and traffic, hazardous materials and hazardous and solid waste. The Draft EIS also includes a discussion of the issue of climate change as it relates to the proposed action.

Three agencies are serving as cooperating agencies in the preparation of the Draft EIS because of their jurisdictional responsibilities and/or special expertise: the Arizona Game and Fish Department, the City of Goodyear, and the Town of Buckeye.

A Notice of Intent to Prepare an EIS for the Proposed Sonoran Solar Energy Project, Maricopa County, Arizona, was published in the **Federal Register** on July 8, 2009 (74 FR 32641). The BLM held three public scoping meetings in Phoenix, Buckeye, and Gila Bend, Arizona, on August 4, 5, and 6, 2009, respectively. The formal 30-day public scoping period ended September 8, 2009.

All timely comments on the Draft EIS will be considered in the preparation of the Final EIS, currently scheduled for release in the fall of 2010. Please include the commenter's name and street address. All substantive comments and information submitted will be summarized and addressed in the Final EIS.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10.

James G. Kenna,

State Director.

[FR Doc. 2010–8909 Filed 4–16–10; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVE02000 L51100000.GN0000 LVEMF1000570 241A; MO:4500011675; 10–08807; TAS: 14X5017]

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Hollister Underground Mine Project, Elko County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended, (NEPA) and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Tuscarora Field Office, Elko, Nevada, intends to prepare an Environmental Impact Statement (EIS) and by this notice is announcing the beginning of the scoping process to solicit public comments and to identify issues.

DATES: This notice initiates the public scoping process for the EIS. Comments on issues may be submitted in writing until May 19, 2010. The date(s) and location(s) of any scoping meetings will be announced at least 15 days in advance through local media, newspapers and the BLM Web site at: *http://www.blm.gov/nv/st/en/fo/elko_field_office.html.* In order to be included in the Draft EIS, all comments must be received prior to the close of the scoping period or 15 days after the last public meeting, whichever is later. The BLM will provide additional opportunities for public participation upon publication of the Draft EIS.

ADDRESSES: You may submit comments related to the Hollister Underground Mine Project by any of the following methods:

- *Web site: http://www.blm.gov/nv/st/en/fo/elko_field_office.html.*
- *E-mail: janice_stadelman@blm.gov.*
- *Fax:* (775) 753–0255.
- *Mail:* BLM Tuscarora Field Office, Attn. Janice Stadelman, 3900 Idaho Street, Elko, Nevada 89801.

Documents pertinent to this proposal may be examined at the Tuscarora Field Office.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to the mailing list, contact Janice Stadelman, Project Lead, telephone (775) 753–0346; address 3900 Idaho St., Elko, Nevada 89801; e-mail *janice_stadelman@blm.gov.*

SUPPLEMENTARY INFORMATION: Rodeo Creek Gold Inc. has proposed an amendment to their plan of operations for the Hollister Underground Mine Project. The proposed amendment would expand Rodeo Creek Gold Inc.'s existing underground exploration activities into a full-scale underground mining operation. Most of the necessary infrastructure to support full-scale mining was authorized and built in conjunction with the underground exploration activities. Currently, the project has created 66 acres of approved surface disturbance on public lands, of which approximately 75 percent of the existing facilities are located on previously disturbed ground within an existing open pit mine. The proposed expansion to full-scale mining would disturb an additional 58 acres of public land for a total of 124 acres of surface disturbance. The proposed action consists of constructing a new production shaft; improving existing roads; building a power transmission line to the mine site; upgrading ancillary facilities including storage areas, office, shop, and warehouse buildings; and continuing both surface and underground exploration. The full-scale project would augment the existing mine water management facilities that currently include a reverse-osmosis and desilting water treatment plant and rapid infiltration basins by adding underground dewatering wells and obtaining a National Pollutant Discharge Elimination System permit to authorize discharge of groundwater to Little Antelope Creek. The Hollister Project would haul the mined ore using highway-legal trucks to existing off-site milling facilities via existing roads that would be improved as needed; no on-site processing facilities are proposed. The project is expected to operate for 20 years. The proposed project is located in and adjacent to the Tosawihi Quarries Archaeological District and near the Tosawihi Quarries Traditional Cultural Properties (TCP), 47 miles northwest of Elko, Nevada, in Elko County.

The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the process for developing the EIS. At present, the BLM has identified the following preliminary issues: cultural resources, Native American religious concerns, hydrology, and noise.

The BLM will use and coordinate the NEPA commenting process to satisfy the public involvement process for Section 106 of the National Historic Preservation Act, 16 U.S.C. 470f, as provided for in 36 CFR 800.2(d)(3). Native American tribal consultations will be conducted and Tribal concerns will be given due consideration, including impacts on Indian trust assets, if any. Federal, State, and local agencies, along with other stakeholders that may be interested or affected by the BLM's decision on this project are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate as a cooperating agency.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1501.7.

Kenneth E. Miller,

Manager, Elko District Office.

[FR Doc. 2010–8906 Filed 4–16–10; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CACA 048880, LLCAD06000, L51010000.FX0000, LVRWB09B2520]

Notice of Availability of the Draft Environmental Impact Statement/Staff Assessment for the NextEra Energy Resources Genesis Solar Energy Project and Possible California Desert Conservation Area Plan Amendment

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) and the California Energy Commission (CEC) have prepared a Draft Environmental Impact Statement (EIS), Draft California Desert Conservation Area (CDCA) Plan Amendment, and Staff Assessment (SA) as a joint environmental analysis document for the Genesis Solar Energy Project (GSEP), Riverside County, California, and by this notice are announcing the opening of the comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Draft EIS/SA and plan amendment within 90 days

following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**. The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: You may submit comments related to the GSEP by any of the following methods:

• *E-mail: CAPSSolarNextEraFPL@blm.gov.*

• *Mail or other delivery service:* Allison Shaffer, Project Manager, Palm Springs South Coast Field Office, Bureau of Land Management, 1201 Bird Center Drive, Palm Springs, California 92262.

Copies of the GSEP Draft EIS/SA are available from the BLM at the above addresses.

FOR FURTHER INFORMATION CONTACT: Allison Shaffer, BLM project manager, at (760) 833–7100. *See* also **ADDRESSES** above.

SUPPLEMENTARY INFORMATION: NextEra Energy Resources has submitted a right-of-way (ROW) application to the BLM for development of the proposed GSEP on public lands, consisting of two concentrating solar electric generating power plants each producing 125 megawatts (MW) for a total output of approximately 250 MW of electricity at full development. The project would use a wet-cooling tower for power plant cooling. Water for the project (approximately 1,644 acre-feet per year) would be obtained from on-site wells. The project would include a 15-mile transmission line to the Colorado River Substation; 5.6 miles of this line would use the existing 230-kilovolt Blythe Energy Transmission Line. The total expected project footprint is about 1,800 acres of BLM-managed lands for the two power plants, and approximately 80 to 90 acres in support of ancillary facilities. The project is sited in an undeveloped area of the Sonoran Desert, near Ford Dry Lake, north of Interstate 10 in Riverside County, approximately 25 miles west of Blythe, California, on lands managed by the BLM. The BLM's purpose and need for the GSEP is to respond to NextEra's application for a ROW grant to construct, operate, and decommission a solar power facility on public lands in compliance with Title V of FLPMA (43 U.S.C. 1761), BLM ROW regulations, and other applicable Federal laws. The BLM will decide whether to grant, grant with modification, or deny a ROW to NextEra for the proposed GSEP. The BLM will also consider amending the CDCA Plan (1980, as amended) in this analysis. The CDCA Plan, while recognizing the potential compatibility of solar generation facilities on public lands, requires that all sites proposed for power generation or transmission not identified in the Plan be considered through the BLM land use plan amendment process. If the BLM decides to grant a ROW for this project, the CDCA Plan would be amended as required.

The proposed action is to authorize the GSEP and amend the CDCA Plan to designate the project area as available for solar energy projects. In addition to the proposed action, the BLM is analyzing an alternative that would reduce the project footprint by half, to approximately 900 acres of disturbance, by constructing only one power plant for a total output of 125 MW. The BLM is also analyzing a dry-cooling alternative. All three action alternatives would amend the CDCA Plan to designate the area as available for commercial solar energy development. As required under NEPA, the Draft EIS analyzes a No Action alternative that would not require a CDCA Plan amendment. The Draft EIS also analyzes alternatives that reject the project, but amend the CDCA Plan to either: (1) Designate the project area as available for future solar energy power generation projects; or (2) designate the project area as unavailable for future solar energy power generation projects. The BLM will take into consideration the provisions of the Energy Policy Act of 2005 and Secretarial Order 3283 *Enhancing Renewable Energy Development on the Public Lands* and Secretarial Order 3285 *Renewable Energy Development by the Department of the Interior* in responding to the NextEra application.

The BLM has entered into a Memorandum of Understanding with the CEC to conduct a joint environmental review of solar thermal projects that are proposed on Federal land managed by the BLM. The BLM and CEC have agreed to conduct joint environmental review of the project in a single combined NEPA/California Environmental Quality Act process and document. The Draft EIS/SA analyzes site-specific impacts of the proposed project on air quality; biological, cultural, water, soil, visual, paleontological, and geological resources; recreation; land use; noise; public health; socioeconomics; and traffic and transportation. The Draft EIS/SA also addresses hazardous materials handling, waste management, worker safety, fire protection, facility design engineering, efficiency, reliability, transmission system engineering, transmission line safety, and nuisance.

A Notice of Intent to Prepare an EIS/SA and Proposed Land Use Plan Amendment for the NextEra Genesis Solar Energy Project in Riverside County was published in the **Federal Register** on November 23, 2009 (74 FR 61167). The BLM held two public scoping meetings in Blythe, California, and Palm Desert, California, on December 10th and11th, 2009. The formal scoping period ended December 23, 2009.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 1506.10, and 43 CFR 1610.2

Karla D. Norris,

Associate Deputy State Director.

[FR Doc. 2010–8905 Filed 4–16–10; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

National Park Service

Cape Cod National Seashore; South Wellfleet, Massachusetts; Cape Cod National Seashore Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Two hundredth seventy-third notice of meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App 1, Section 10) of a meeting of the Cape Cod National Seashore Advisory Commission.

DATES: The meeting of the Cape Cod National Seashore Advisory Commission will be held on May 24, 2010 at 1 p.m.

ADDRESSES: The Commission members will meet in the meeting room at Headquarters, 99 Marconi Station, Wellfleet, Massachusetts.

SUPPLEMENTARY INFORMATION: The Commission was reestablished pursuant to Public Law 87–126 as amended by Public Law 105–280. The purpose of the Commission is to consult with the Secretary of the Interior, or his designee, with respect to matters relating to the

development of Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

The regular business meeting is being held to discuss the following:

1. Adoption of Agenda.
2. Approval of Minutes of Previous Meeting, (March 22, 2010).
3. Reports of Officers.
4. Reports of Subcommittees.
5. Superintendent's Report.

- Update on Dune Shacks
- Improved Properties/Town Bylaws
- Herring River Wetland Restoration
- Wind Turbines/Cell Towers
- Shorebird Management
- Highlands Center Update
- Alternate Transportation funding
- Other construction projects
- Land Protection
- Salt Pond Visitor Center exhibit update
- Storm Damage

6. Old Business.
7. New Business.
8. Date and agenda for next meeting.
9. Public comment.
10. Adjournment.

The meeting is open to the public. It is expected that 15 persons will be able to attend the meeting in addition to Commission members.

Interested persons may make oral/written presentations to the Commission during the business meeting or file written statements. Such requests should be made to the park superintendent prior to the meeting. 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.

FOR FURTHER INFORMATION CONTACT: Further information concerning the meeting may be obtained from the Superintendent, Cape Cod National Seashore, 99 Marconi Site Road, Wellfleet, MA 02667.

April 6, 2010.

George E. Price, Jr.

Superintendent.

[FR Doc. 2010–8972 Filed 4–16–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Glen Canyon Dam Adaptive Management Work Group (AMWG)

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of public meeting (webinar conference call).

SUMMARY: The Glen Canyon Dam Adaptive Management Program (AMP) was implemented as a result of the Record of Decision on the Operation of Glen Canyon Dam Final Environmental Impact Statement to comply with consultation requirements of the Grand Canyon Protection Act (Pub. L. 102–575) of 1992. The AMP includes a Federal advisory committee (AMWG), a technical work group (TWG), a monitoring and research center, and independent review panels. The AMWG makes recommendations to the Secretary of the Interior concerning Glen Canyon Dam operations and other management actions to protect resources downstream of Glen Canyon Dam consistent with the Grand Canyon Protection Act. The TWG is a subcommittee of the AMWG and provides technical advice and recommendations to the AMWG.

DATE AND TIME: The May 6, 2010, AMWG meeting will begin at 2 p.m. (EDT), 12 p.m. (MDT), and 11 a.m. (PDT) and conclude three (3) hours later in the respective time zones.

Conference Call Phone Number: The dial in number for the conference call is 203–320–3258; the pass code is: 1421568. The toll free number is: 888–790–7012; the pass code is: 1421568. There will be limited ports available, so if you wish to participate, please contact Linda Whetton at 801–524–3880 by April 30, 2010, to register.

Webex Webinar Information: In addition to the conference call line, a WebEx webinar has been set up for this meeting. The WebEx webinar Web site for the May 6, 2010 AMWG meeting is: *https://usgs.webex.com/usgs/j.php?ED=135461657&UID=1123935522.* The WebEx webinar does not have audio functionality so if you plan to participate in the webinar, you must dial into the telephone number listed above.

If you plan to participate in the meeting via WebEx, please ensure your system is able to connect by going to *http://www.webex.com/lp/jointest/.* You can also "take a tour" at *http://www.webex.com/go/quick_tour.*

A one hour "test run" will be conducted on Wednesday, April 21, 2010, at 2 p.m. (EDT), 12 p.m. (MDT), and 11 a.m. (PDT) to ensure that the connections work properly. The one hour test Web site is: *https://usgs.webex.com/usgs/j.php?ED=135461697&UID=1123935637.*

Note: If you have difficulties accessing the test or AMWG meeting using the Web sites above, attendees can browse for the WebEx meeting from the main USGS WebEx page: *http://usgs.webex.com.* Enter "Glen Canyon Dam" in the search box at the top of the page, and then click on the meeting in which you would like to participate. Recognizing some computers may have difficulty accessing the platform, you are encouraged to call the WebEx number for technical assistance: 866–229–3239. If you cannot do the test run, contact Mary Daugherty (928–556–7217) at the Grand Canyon Monitoring and Research Center and arrange another time.

To view a copy of the agenda and documents related to the above meeting, please visit Reclamation's Web site at: *http://www.usbr.gov/uc/rm/amp/amwg/mtgs/10may06CC/index.html.*

ADDRESSES: Time will be allowed for any individual or organization wishing to make formal oral comments on the call. To allow for full consideration of information by the AMWG members, written notice must be provided to Dennis Kubly, Bureau of Reclamation, Upper Colorado Regional Office, 125 South State Street, Room 6107, Salt Lake City, Utah, 84138; telephone 801–524–3715; facsimile 801–524–3858; e-mail at *dkubly@usbr.gov* at least five (5) days prior to the call. Any written comments received will be provided to the AMWG members.

FOR FURTHER INFORMATION CONTACT: Dennis Kubly, Bureau of Reclamation, telephone 801–524–3715; facsimile 801–524–3858; e-mail at *dkubly@usbr.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the conference call will be for the AMWG to review the AMP Proposed New Budget Process and Draft Budget for Fiscal Years 2011–12.

Before including your name, 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: April 13, 2010.

Dennis Kubly,

Chief, Adaptive Management Group, Environmental Resources Division, Upper Colorado Regional Office, Salt Lake City, Utah.

[FR Doc. 2010–8896 Filed 4–16–10; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,291]

Modine Manufacturing Company, Pemberville, OH; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated March 10, 2010, a petitioner requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of the subject firm. The determination was issued on February 12, 2010. The Notice of Determination was published in the **Federal Register** on March 12, 2010 (75 FR 11925).

The initial investigation resulted in a negative determination based on the finding that imports of Class 8 heavy duty trucks did not contribute importantly to worker separations at the subject firm and no shift of production to a foreign source occurred.

In the request for reconsideration, the petitioner provided additional information pertaining to the articles manufactured at the subject firm and to customers of the subject firm.

The Department has carefully reviewed the request for reconsideration and the existing record and has determined that the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 1st day of April, 2010.

Del Min Amy Chen,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8873 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–70,599]

Innovion Corporation, Gresham, Oregon; Notice of Affirmative Determination Regarding Application for Reconsideration

On March 16, 2010, the Department received the petitioner's application (dated March 2, 2010) requesting administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of the subject firm. The determination was issued on December 15, 2009, and the Notice of Determination was published in the **Federal Register** on February 16, 2010 (75 FR 7034).

The initial investigation resulted in a negative determination based on the findings that there was no increase in imports or shift/acquisition of ion implantation services by the workers' firm or customers. The workers' separations were held to be attributable to a major customer cancelling a contract with the workers' firm in order to perform ion implantation services in-house.

In the request for reconsideration, the petitioner provided additional information regarding customers of the subject firm.

The Department has carefully reviewed the request for reconsideration and the existing record, and has determined that the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 31st day of March, 2010.

Del Min Amy Chen,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8872 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,052]

Chrysler LLC, St. Louis North Assembly Plant, Including On-Site Leased Workers From HAAS TCM, Inc., Logistics Services, Inc., Diversified Contract Service, Inc. #639, and Logistics Management Services, Inc., Fenton, MO; 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 April 14, 2008, applicable to workers of Chrysler LLC, St. Louis North Assembly Plant, Fenton, Missouri. The notice was published in the **Federal Register** on May 2, 2008 (73 FR 24317).

The certification was subsequently amended on November 18, 2008 to include on-site leased workers from HAAS TCM, amended on December 9, 2008 to include on-site leased workers from Logistics Services, Inc., and amended on October 30, 2009 to include on-site leased workers from Diversified Contract Service, Inc., #639.

Based on information provided by a representative of the State of Missouri Department of Economic Development, Division of Workforce Development, in a Trade Adjustment Assistance petition (TA–W–72,679) that workers of Logistics Management Services, Inc. worked on-site at the Chrysler LLC, Fenton, Missouri plant (Logistics Management Services, Inc. workers "sequenced the Dodge Ram pickup truck frames to be the first item loaded onto the assembly line") and that the workers' schedules were "under the direct control of the production scheduling department" at the North Assembly Plant, the Department reviewed the certification for workers of the subject firm.

Based on the new information provided by the State of Missouri, the Department is amending this certification to include workers leased from Logistics Management Services, Inc. working on-site at the Fenton, Missouri location of Chrysler LLC.

The intent of the Department's certification is to include all workers

employed at Chrysler LLC, St. Louis North Assembly Plant, Fenton, Missouri who were adversely affected by increased imports of Dodge Ram full-sized pickup trucks.

The amended notice applicable to TA–W–63,052 is hereby issued as follows:

All workers of Chrysler LLC, St. Louis North Assembly Plant, including on-site leased workers from HAAS TCM, Inc., Logistics Services, Inc., Diversified Contract Service, Inc., #639, and Logistics Management Services, Inc., Fenton, Missouri, who became totally or partially separated from employment on or after March 18, 2007, through April 14, 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 31st day of March, 2010.

Del Min Amy Chen,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8880 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,818]

Delphi Thermal Systems Currently Known as General Motors Components Holdings LLC, Lockport Operations, Lockport, NY; 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 September 25, 2008, applicable to workers of Delphi Thermal Systems, Lockport Operations, Lockport, New York. The notice was published in the **Federal Register** on October 8, 2008 (73 FR 58981).

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of automotive heat exchanger products and HVAC modules.

New information shows that following a bankruptcy agreement, Delphi Thermal Systems was taken over by General Motors and is currently known as General Motors Components Holdings LLC. Workers separated from employment at the subject firm had their wages reported under two separate unemployment insurance (UI) tax accounts under the names of General Motors Components Holdings LLC and Delphi Thermal Systems.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Delphi Thermal Systems, currently known as General Motors Components Holdings LLC, Lockport, New York, who were adversely affected by imports of articles like or directly competitive with automotive heat exchanger products and HVAC modules.

The amended notice applicable to TA–W–63,818 is hereby issued as follows:

All workers of Delphi Thermal Systems, currently known as General Motors Components Holdings LLC, Lockport Operations, Lockport, New York, who became totally or partially separated from employment on or after August 4, 2007 through September 25, 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 in Washington, DC, this 6th day of April 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8881 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–64,633]

Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Hewlett Packard Company, Imaging and Printing Group, Edgeline Development & Light Production Systems (LPS), Operations Division, Edgeline Development and Operations, Including On-Site Leased Workers from Adecco, ATA Engineering, Inc., CCSI, Inc., Collabers (Formerly Global Consultants, Inc.), COMSYS Information Technology Services, Inc., Conficio, LLC, DB Professionals, Inc., Everest Consultants, Inc., Global Consultants, Inc., H.L. Yoh Company LLC, Manpower, Inc., Netsource, Inc., Quality Logic, Inc., Spherion Corporation, Stilwell Baker, Stratus Global Partners, Syncro Design, LLC, Techlink Systems, Technical Aid Corp., D.B.A. TAC Worldwide Company, Trinite, Inc., Volt Information Sciences, Inc., K Force, SHI, and Supply Source, Vancouver, Washington.

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 December 19, 2008 applicable to workers of Hewlett Packard Company, Imaging and Printing Group, Edgeline Development & Light Production Systems (LPS) Operations Division, Edgeline Development and Operations, including on-site leased workers from Adea Solutions Company, Artech Information Systems, ATP Personnel Services Corporation, CDI Corporation, Finesse Personnel Associates (W.C. Barlow & Associates), Hightower Technology Capital, Inc., Kelly Services, Inc., Lionbridge Technologies, Inc., (AKA Veritest), Northwest Software, Inc., PDG (Product Design Group), Radiant Systems, Inc., Siemens, Inc., Synova, Inc., Technical Aid Corporation, d/b/a TAC Worldwide Company, and Volt Information Sciences, Inc. The notice was published in the **Federal Register** on January 14, 2009 (74 FR 2136).

At the request of a petitioner, the Department reviewed the certification for workers of the subject firm. The workers produce engineering specifications, software, and firmware used in the manufacture of HP Edgeline printers. An important part of this work involved the production and testing of printer prototypes.

New information shows that workers leased from the above mentioned firms were employed on-site at the Vancouver, Washington location of Hewlett Packard Company, Imaging and Printing Group, Edgeline Development & Light Production Systems (LPS) Operations Division, Edgeline Development and Operations. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from the above mentioned firms working on-site at the Vancouver, Washington location of Hewlett Packard Company, Imaging and Printing Group,

Edgeline Development & Light Production Systems (LPS) Operations Division, Edgeline Development and Operations.

The amended notice applicable to TA–W–64,633 is hereby issued as follows:

All workers of Hewlett Packard Company, Imaging and Printing Group, Edgeline Development and Light Production Systems (LPS) Operations, Edgeline Development Operations, Vancouver, Washington, including on-site leased workers from Adea Solutions Company, Artech Information Systems, ATP Personnel Services Corporation, CDI Corporation, Finesse Personnel Associates (W.C. Barlow & Associates), Hightower Technology Capital, Inc., Kelly Services, Inc., Lionbridge Technologies, Inc. (aka VeriTest), Northwest Software, Inc., PDG (Product Design Group), Radiant Systems, Inc., Siemens, Inc., Synova, Inc., Technical Aid Corporation d/b/a TAC Worldwide Company, Volt Information Sciences, Inc., Adecco, ATA Engineering, Inc., CCSI, Inc., Collabera, (formerly known as Global Consultants, Inc.), COMSYS Information Technology Services, Inc., Conficio, LLC, DB Professionals, Inc., Everest Consultants, Inc., Global Consultants, Inc., H.L. Yoh Company, LLC. Manpower, Inc., NetSource, Inc., Quality Logic, Inc., Spherion Corporation, Stilwell Baker, Stratus Global Partners, Syncro Design, LLC, TechLink Systems, Technical Aid Corp., d/b/a TAC Worldwide Company, Trinite, Inc., K Force, SHI and Supply Source, who became totally or partially separated from employment on or after December 3, 2007 through December 19, 2010, through April 27, 2011, 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 12th day of April 2009.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8882 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–65,797]

ABB, Inc., Including On-Site Leased Workers From Spherion Staffing, Dividend Staffing, Mystaff, and Zero Chaos, Wichita Falls, TX; 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, as amended (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 17, 2009, applicable to workers of ABB Inc., Wichita Falls, Texas. The notice was published in the **Federal Register** July 14, 2009 (74 FR 34038).

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of electrical components.

New information shows that workers leased from Spherion Staffing, Dividend Staffing, MyStaff, and Zero Chaos were employed on-site by the Wichita Falls, Texas location of ABB, Inc. The Department has determined that these workers were sufficiently under the control and in support of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Spherion Staffing, Dividend Staffing, MyStaff, and Zero Chaos working on-site at the Wichita Falls, Texas location of ABB, Inc.

The amended notice applicable to TA–W–65,797 is hereby issued as follows:

All workers of ABB, Inc., include on-site leased workers from Spherion Staffing, Dividend Staffing, MyStaff, and Zero Chaos Wichita Falls, Texas, who became totally or partially separated from employment on or after April 13, 2008 through June 17, 2011 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 in Washington, DC this 7th day of April 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8883 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,052]

Chrysler LLC, St. Louis North Assembly Plant, Including On-Site Leased Workers From Haas TCM, Inc., Logistics Services, Inc. Diversified Contract Service, Inc. #639, and Logistics Management Services, Inc. Fenton, MO; 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 April 14, 2008, applicable to workers of Chrysler LLC, St. Louis North Assembly Plant, Fenton, Missouri. The notice was published in the **Federal Register** on May 2, 2008 (73 FR 24317).

The certification was subsequently amended on November 18, 2008 to include on-site leased workers from HAAS TCM, amended on December 9, 2008 to include on-site leased workers from Logistics Services, Inc., and amended on October 30, 2009 to include on-site leased workers from Diversified Contract Service, Inc., #639.

Based on information provided by a representative of the State of Missouri Department of Economic Development, Division of Workforce Development, in a Trade Adjustment Assistance petition (TA–W–72,679) that workers of Logistics Management Services, Inc. worked on-site at the Chrysler LLC, Fenton, Missouri plant (Logistics Management Services, Inc. workers "sequenced the Dodge Ram pickup truck frames to be the first item loaded onto the assembly line") and that the workers' schedules were "under the direct control of the production scheduling department" at the North Assembly Plant, the Department reviewed the certification for workers of the subject firm.

Based on the new information provided by the State of Missouri, the Department is amending this certification to include workers leased from Logistics Management Services, Inc. working on-site at the Fenton, Missouri location of Chrysler LLC.

The intent of the Department's certification is to include all workers

employed at Chrysler LLC, St. Louis North Assembly Plant, Fenton, Missouri who were adversely affected by increased imports of Dodge Ram full-sized pickup trucks.

The amended notice applicable to TA–W–63,052 is hereby issued as follows:

All workers of Chrysler LLC, St. Louis North Assembly Plant, including on-site leased workers from HAAS TCM, Inc., Logistics Services, Inc., Diversified Contract Service, Inc., #639, and Logistics Management Services, Inc., Fenton, Missouri, who became totally or partially separated from employment on or after March 18, 2007, through April 14, 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 31st day of March, 2010.

Del Min Amy Chen,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8869 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–72,575]

Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

Dell Products LP, Winston-Salem (WS–1) Division, Including On-Site Leased Workers From Adecco, Spherion, Patriot Staffing, Manpower, Teksystems, APN, ICONMA and Staffing Solutions, South East Winston-Salem, North Carolina

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on March 1, 2010, applicable to workers of Dell Products LP, Winston-Salem (WS–1) Division, including on-site leased workers of Adecco, Spherion, Patriot Staffing, Manpower, TEKsystems, APN, and ICONMA, Winston-Salem, North Carolina. The notice will be published soon in the **Federal Register**.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in production of desktop computers.

The company reports that workers leased from Staffing Solutions, South East were employed on-site at the Winston-Salem, North Carolina location of Dell Products LP, Winston-Salem (WS–1) Division. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Staffing Solutions, South East working on-site at the Winston-Salem, North Carolina location of Dell Products LP, Winston-Salem (WS–1) Division.

The amended notice applicable to TA–W–72,575 is hereby issued as follows:

All workers of Dell Products LP, Winston-Salem (WS–1) Division, including on-site leased workers from Adecco, Spherion, Patriot Staffing, Manpower, TEKsystems, APN, ICONMA and Staffing Solutions, South East, Winston-Salem, North Carolina, who became totally or partially separated from employment on or after October 13, 2008, through March 1, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC, this 30th day of March 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8865 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–70,520; TA–W–70,520A]

Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

TA–W–70,520, The Boeing Company, Commercial Aircraft Group, Including On-Site Leased Workers from Comforce Corporation, Adecco, Multax, Inconen, CTS, Hi-Tec, Woods, Ciber, Kelly Services, Analysts International Corp, Comsys, Filter LLC, Excell, Entegee, Chipton-Ross, Ian Martin, Can-Tech, IT Services, IDEX Solutions (NWCAD), Media Logic, HL YOH, Volt, PDS, CDI Corp, Teksystems, Innovative Systems, Inc., Murphy & Associates, Dell, PFI Tech, and RMS Puget Sound, Washington.

TA–W–70,520A, The Boeing Company, Commercial Aircraft Group, Including On-Site Leased Workers from Comforce Corporation, Adecco, Multax, Inconen, CTS, Hi-Tec, Woods, Ciber, Kelly Services, Analysts International Corp, Comsys, Filter LLC, Excell, Entegee, Chipton-Ross, Ian Martin, Can-Tech, IT Services, IDEX Solutions (NWCAD), Media Logic, HL YOH, Volt, PDS, CDI Corp, Teksystems, Innovative Systems, Inc., Murphy & Associates, Dell, Pfi Tech, and RMS Portland, Oregon.

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on October 19, 2009, applicable to workers of The Boeing Company, Commercial Aircraft Group, Puget Sound, Washington, (TA–W–70,520), and The Boeing Company, Commercial Aircraft Group, Portland, Oregon (TA–W–70,520A). The notice was published in the **Federal Register** on December 11, 2009 (74 FR 65794–65795). The notice was amended on January 8, 2010 to include on-site leased workers. The notice was published in the **Federal Register** on January 20, 2010 (75 FR 3250–3251). The workers are engaged in activities related to the production of large commercial aircraft.

The company reports that on-site leased workers from Dell, PFI Tech, and RMS were also employed on-site at both the Puget Sound, Washington and Portland, Oregon locations of The Boeing Company, Commercial Aircraft Group. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending the certification to include leased workers from Dell, PFI Tech, and RMS working on-site at the Puget Sound, Washington and Portland, Oregon locations of The Boeing Company, Commercial Aircraft Group.

The amended notice applicable to the TA–W–70,520 and TA–W 70,520A is hereby issued as follows:

"All workers of The Boeing Company, Commercial Aircraft Group, including on-site leased workers from Comforce Corporation, Adecco, Multax, Inconen, CTS, Hi-Tec, Woods, Ciber, Kelly Services, Analysts International Corp, Comsys, Filter LLC, Excell, Entegee, Chipton-Ross, Ian Martin, Can-Tech, IT Services, IDEX Solutions (NWCAD), Media Logic, HL YOH, Volt, PDS, CDI Corp, Teksystems, Innovative Systems, Inc., Murphy & Associates, Dell, PFI Tech, and RMS, Puget Sound, Washington (TA–W–70,520), and Portland, Oregon (TA–W–70,520A), who became totally or partially separated from employment on or after May 22, 2008, through October 19, 2011, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended."

Signed in Washington, DC, this 26th day of March 2010.

Michael W. Jaffe,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8871 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,482]

Trane a Subsidiary of Ingersoll Rand Including On-Site Leased Workers From Aerotek, Express Personnel Services, Select Staffing, and Industrial Mechanical Contractors, Inc. Pueblo, CO; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 22, 2010, applicable to workers of Trane, a subsidiary of Ingersoll Rand, including on-site leased workers from Aerotek, Express Personnel Staffing, and Select Staffing, Pueblo, Colorado. The notice was published in the **Federal Register** on March 5, 2010 (75 FR 10320).

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of air conditioning equipment.

The company reports that workers leased from Industrial Mechanical Contractors, Inc. were employed on-site at the Pueblo, Colorado location of Trane, a subsidiary of Ingersoll Rand. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Industrial Mechanical Contractors, Inc. working on-site at the Pueblo, Colorado location of Trane, a subsidiary of Ingersoll Rand.

The amended notice applicable to TA–W–71,482 is hereby issued as follows:

All workers of Trane, a subsidiary of Ingersoll Rand, including on-site leased workers from Aerotek, Express Personnel Staffing, Select Staffing, and Mechanical Contractors, Inc., Pueblo, Colorado, who became totally or partially separated from employment on or after June 22, 2008, through January 22, 2012, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 6th day of April, 2010.

Michael W. Jaffe,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8891 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,321]

Auburn Hosiery Mills, Inc., Currently Known as Delta Galil, Including On-Site Leased Workers From Quality Personnel, Auburn, KY; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on July 8, 2009, applicable to workers of Auburn Hosiery Mills, Inc., including on-site leased workers from Quality Personnel, Auburn, Kentucky. The notice was published in the **Federal Register** on August 19, 2009 (74 FR 41933).

At the request of the state agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to distribution, administration and quality control services related to apparel.

Information shows that Auburn Hosiery Mills was merged into its parent company, Delta Galil on January 1, 2010 and is now known as Delta Galil. Some of the workers separated from employment at the subject firm had their wages reported under a separate unemployment insurance (UI) tax account under the name of Delta Galil.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by the shift in distribution, administration and quality control services to Bangladesh and China.

The amended notice applicable to TA–W–71,321 is hereby issued as follows:

All workers of Auburn Hosiery Mills, Inc., Delta Galil, including on-site leased workers from Quality Personnel, Auburn, Kentucky, who became totally or partially separated from employment on or after June 18, 2008, through July 8, 2011, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 5th day of April, 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8890 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,251]

AMTEX Incorporated, a Subsidiary of Hayashi Telepu Company, Including On-Site Leased Workers of Availability Personnel Services, Conerstone Staffing Solutions, Priority Business Services and Volt, Inc. Manteca, CA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on March 16, 2010. The notice will be published in the **Federal Register** soon.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of interior automotive carpet.

The company reports that workers leased from Volt, Inc. were employed on-site at the Manteca, California location of Amtex, Inc., a subsidiary of Hayashi Telepu Company. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Volt, Inc. working on-site at the Manteca, California location of Amtex, Inc., a subsidiary of Hayashi Telepu Company.

The amended notice applicable to TA–W–73,251 is hereby issued as follows:

All workers of Amtex, Inc., a subsidiary of Hayashi Telepu Company, including on-site leased workers of Availability Personnel Services, Cornerstone Staffing Solutions, Priority Business Services and Volt, Inc, Manteca, California, who became totally or partially separated from employment on or after January 12, 2009 through March 16, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 8th day of April 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8894 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–72,649]

Contech Castings, LLC, Including Workers Whose Unemployment Insurance (UI) Wages Are Reported Through Contech Us LLC, Including On-Site Leased Workers From On Staff USA, Dowagiac, MI; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (“Act”), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on February 23, 2010, applicable to workers of Contech Castings, LLC, including on-site leased workers from On Staff USA, Dowagiac, Michigan. The notice will soon be published in the **Federal Register**.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of aluminum and magnesium die casted component parts for automobiles.

New information shows that the assets of Contech US LLC were purchased in June 2009 and a new company, Contech Casting LLC was formed. Some workers separated from employment at the subject firm had their wages reported under a separate unemployment insurance (UI) tax account under the name of Contech US LLC.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department’s certification is to include all workers of the subject firm who were adversely affected by increased imports of aluminum and magnesium die casted component parts for automobiles.

The amended notice applicable to TA–W–72,649 is hereby issued as follows:

All workers of Contech Castings, LLC, including workers whose UI wages are reported through Contech US LLC, including on-site leased workers from On Staff USA, Dowagiac, Michigan, who became totally or partially separated from employment on or after October 19, 2008, through February 23, 2012, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 6th day of April 2010.

Elliott S. Kushner

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8893 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–72,075; TA–W–72,075D; TA–W–72,075E]

Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

TA–W–72,075, Assembly & Test Worldwide, Inc., Livonia, Michigan.
TA–W–72,075D, Assembly & Test Worldwide, Inc., Lake Zurich, Illinois.
TA–W–72,075E, Assembly & Test Worldwide, Inc., Shelton, Connecticut.

In accordance with Section 223 of the Trade Act of 1974, as amended (“Act”), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 27, 2010, applicable to workers of Assembly & Test Worldwide, Inc., Livonia, Michigan. The notice was published in the **Federal Register** on March 5, 2010 (75 FR 10321). At the request of a company official, the Department reviewed the certification for workers of the subject firm. The workers design, engineer, manufacture and integrate custom component assembly and test systems.

The company reports that the worker group also includes workers at the Lake Zurich, Illinois and Shelton, Connecticut locations of the subject firm that were inadvertently omitted from the Department’s decision.

Accordingly, the Department is amending this certification to include workers of the Lake Zurich, Illinois and Shelton, Connecticut locations of the subject firm.

The intent of the Department’s certification is to include all workers of the subject firm who were adversely affected by the shift in production of custom component assembly and test systems to Brazil, China and Germany.

The amended notice applicable to TA–W–72,075 is hereby issued as follows:

All workers of Assembly & Test Worldwide, Inc., Livonia, Michigan (TA–W–72,075); Assembly & Test Worldwide, Inc., Saginaw, Michigan (TA–W–72,075A); Assembly & Test Worldwide, Inc., Lebanon, Missouri (TA–W–72,075B); Assembly & Test Worldwide, Inc., Dayton, Ohio (TA–W–72,075C); Assembly & Test Worldwide, Lake Zurich, Illinois (TA–W–72,075D); and Assembly & Test Worldwide, Shelton, Connecticut (TA–W–72,075E), who became totally or partially separated from employment on or after August 10, 2008, through January 27, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC this 6th day of April 2010.

Michael W. Jaffe,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8892 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,272; TA–W–71,272A; TA–W–71,272B; TA–W–71,272C; TA–W–71,272D; TA–W–71,272E; TA–W–71,272F; TA–W–71,272G; TA–W–71,272H; TA–W–71,272I; TA–W–71,272J; TA–W–71,272K; TA–W–71,272L; TA–W–71,272M; TA–W–71,272N; TA–W–71,272O]

Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

TA–W–71,272, Crucible Materials Corporation, Syracuse, New York.

TA–W–71,272A, Crucible Materials Corporation, Crucible Service Center, Auburn, Massachusetts.
TA–W–71,272B, Crucible Materials Corporation, Crucible Service Center, Meadville, Pennsylvania.
TA–W–71,272C, Crucible Materials Corporation, Crucible Service Center, Troy, Michigan.
TA–W–71,272D, Crucible Materials Corporation, Crucible Service Center, Butler, Wisconsin.
TA–W–71,272E, Crucible Materials Corporation, Crucible Service Center, Miamisburg, Ohio.
TA–W–71,272F, Crucible Materials Corporation, Crucible Service Center, Chicago, Illinois.
TA–W–71,272G, Crucible Materials Corporation, Crucible Service Center, Minneapolis, Minnesota.
TA–W–71,272H, Crucible Materials Corporation, Crucible Service Center, Charlotte, North Carolina.
TA–W–71,272I, Crucible Materials Corporation, Crucible Service Center, Huntsville, Alabama.
TA–W–71,272J, Crucible Materials Corporation, Crucible Service Center, Arlington, Texas.
TA–W–71,272K, Crucible Materials Corporation, Crucible Service Center, Grand Rapids, Michigan.
TA–W–71,272L, Crucible Materials Corporation, Crucible Service Center, St. Louis, Missouri.
TA–W–71,272M, Crucible Materials Corporation, Crucible Service Center, Cleveland, Ohio.
TA–W–71,272N, Crucible Materials Corporation, Crucible Service Center, Valley View, Ohio.
TA–W–71,272O, Crucible Materials Corporation, Crucible Service Center, Romeoville, Illinois.

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on December 14, 2009, applicable to the workers of Crucible Materials Corporation, Syracuse, New York. The Department's Notice was published in the **Federal Register** on February 16, 2010 (75 FR 7032).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of steel components.

New findings show that a significant proportion or number of workers are separated at each of the above-listed locations of the subject firm during the relevant time period.

Accordingly, the Department is amending this certification to include workers of the Crucible Materials Corporation, Crucible Service Centers located in Auburn, Massachusetts; Meadville, Pennsylvania; Troy, Michigan; Butler, Wisconsin; Miamisburg, Ohio; Chicago, Illinois; Minneapolis, Minnesota; Charlotte, North Carolina; Huntsville, Alabama; Arlington, Texas; Grand Rapids, Michigan; St. Louis, Missouri; Cleveland, Ohio; Valley View, Ohio; and Romeoville, Illinois.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by the increased imports of steel components.

The amended notice applicable to TA–W–71,272 is hereby issued as follows:

"All workers of Crucible Materials Corporation, Syracuse, New York (TA–W–71,272), including the Crucible Service Centers located in Auburn, Massachusetts (TA–W–71,272A); Meadville, Pennsylvania (TA–W–71,272B); Troy, Michigan (TA–W–71,272C); Butler, Wisconsin (TA–W–71,272D); Miamisburg, Ohio (TA–W–71,272E); Chicago, Illinois (TA–W–71,272F); Minneapolis, Minnesota (TA–W–71,272G); Charlotte, North Carolina (TA–W–71,272H); Huntsville, Alabama (TA–W–71,272I); Arlington, Texas (TA–W–71,272J); Grand Rapids, Michigan (TA–W–71,272K); St. Louis, Missouri (TA–W–71,272L); Cleveland, Ohio (TA–W–71,272M), Valley View, Ohio (TA–W–71,272N); and Romeoville, Illinois (TA–W–71,272O) who became totally or partially separated from employment on or after June 16, 2008, through December 14, 2011, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended."

Signed in Washington, DC this 12th day of March, 2010.

Del Min Amy Chen,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8889 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,248]

International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, Cost and Expense Team, Working From Various States in the United States, Including On-Site Leased Workers From Datrose, Inc., Reporting to Armonk, NY; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on July 31, 2009, applicable to workers of International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, Cost and Expense Team working from various states in the United States, reporting to Armonk, New York. The notice will be published soon in the **Federal Register**.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to support for the Global Technology Services Business Unit.

The company reports that workers leased from Datrose, Inc., were employed on-site at the Armonk, New York, location of International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, Cost and Expense Team. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Datrose, Inc., working on-site at the Armonk, New York location of International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, Cost and Expense Team.

The amended notice applicable to TA–W–71,248 is hereby issued as follows:

All workers of International Business Machines Corporation, Global Technology Services Business Unit, Integrated Technology Services, Cost and Expense Team, including on-site leased workers from Datrose, Inc., working in various states but

reporting to Armonk, New York, who became totally or partially separated from employment on or after June 1, 2008, through July 31, 2011, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 8th day of April, 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8888 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,175; TA–W–71,175A]

Resinoid Engineering Corporation Hebron, OH; Resinoid Engineering Corporation Heath, OH; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on January 25, 2010, applicable to workers of Resinoid Engineering Corporation, Hebron, Ohio. The notice was published in the **Federal Register** March 5, 2010 (75 FR 10323).

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of custom molded plastic components.

New findings show that the Heath, Ohio location of Resinoid also experienced an employment decline during the relevant period. Workers at the Heath, Ohio facility produce commutators and are not separately identifiable from the workers at the Hebron facility. These workers directly support the Hebron, Ohio facility of the subject firm.

Accordingly, the Department is amending the certification to cover workers at the Heath, Ohio location of Resinoid.

The intent of the Department's certification is to include all workers of Resinoid who were adversely affected by the loss in sales to a TAA certified firm.

The amended notice applicable to AT–W–71,175 is hereby issued as follows:

All workers of Resinoid Engineering Corporation, Hebron, Ohio (TA–W–71,175) and Heath, Ohio (TA–W–71,175A) who became totally or partially separated from employment on or after June 4, 2008 through January 25, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this day of April 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8887 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,049]

Chrysler Group LLC, Formerly Known as Chrysler LLC, Warren Office Building, Including On-Site Leased Workers from Product Action International, LLC, Warren, Michigan; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on March 19, 2010 applicable to workers of Chrysler Group LLC, formerly known as Chrysler LLC, Warren Office Building, Warren, Michigan. The notice will be published in the **Federal Register** soon.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to production of automobiles.

The company reports that workers leased from Product Action International, LLC were employed on-site at the Warren, Michigan location of Chrysler Group LLC, formerly known as Chrysler LLC, Warren Truck Assembly Plant. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Product Action International, LLC working on-site at the Warren, Michigan location of Chrysler Group LLC, formerly known as Chrysler LLC, Warren Office Building.

The amended notice applicable to TA–W–71,049 is hereby issued as follows:

All workers of Chrysler Group LLC, formerly known as Chrysler LLC, Warren Office Building, including on-site leased workers from Product Action International, LLC, Warren, Michigan, who became totally or partially separated from employment on or after May 27, 2008, through March 19, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 6th day of April, 2010.

Michael W. Jaffe,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8886 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–70,242]

Findlay Industries, Inc., Findlay Ohio Plant One; Including On-Site Leased Workers From Alternative Management Resource, Inc. (AMRI of Findlay) Also Known as Alternative Management Temporary Services Findlay, OH; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on October 13, 2009, applicable to workers of Findlay Industries, Inc., Findlay Plant One, Findlay, Ohio. The notice was published in the **Federal Register** December 11, 2009 (74 FR 65798).

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of automotive and heavy truck interiors.

The company reports that workers leased from Alternative Management Resource, Inc., (AMRI of Findlay), also known as Alternative Management Temporary Services were employed on-site at the Findlay, Ohio location of Findlay Industries, Inc., Findlay Plant One. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Alternative Management Resource, Inc., (AMRI of Findlay), also known as Alternative Management Temporary Services working on-site at the Findlay, Ohio location of Findlay Industries, Inc., Findlay Plant One.

The amended notice applicable to the TA–W–70,242 is hereby issued as follows:

All workers of Findlay Industries, Inc., Findlay Plant One, including on-site leased workers from Alternative Management Resource, Inc., (AMRI of Findlay), also known as Alternative Management Temporary Services, Findlay, Ohio (TA–W–70,242) and Findlay Industries, Inc., Springfield Division, Springfield, Ohio (TA–W–70,242A), who became totally or partially separated from employment on or after May 19, 2008, through October 13, 2011, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 8th day of April, 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8885 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–70,115]

Senco Brands, Inc., fka Senco Products, Inc., Including the On-Site Leased Workers of Manpower, Inc., Express Personnel Services and, Commercial Construction Management and Resources (CCMR), Cincinnati, OH; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended (“Act”), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on December 10, 2009, applicable to workers of Senco Brands, Inc., fka Senco Products, Inc., including the on-site leased workers of Manpower, Inc., and Express Personnel Services, Cincinnati, Ohio. The notice was published in the **Federal Register** on January 25, 2010 (75 FR 3930).

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of automatic nail guns, nails, and staples.

The company reports that workers leased from Commercial Construction Management and Resources (CCMR) were employed on-site at the Cincinnati, Ohio location of Senco Brands, Inc., fka Senco Products, Inc. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Commercial Construction Management and Resource (CCMR) working on-site at the Cincinnati, Ohio location of Senco Brands, Inc., fka Senco Products, Inc.

The amended notice applicable to TA–W–70,115 is hereby issued as follows:

All workers of Senco Brands, Inc., fka Senco Products, Inc., including the on-site leased workers of Manpower, Inc., Express Personnel Services, and Commercial Construction Management and Resources (CCMR), Cincinnati, Ohio, who became totally or partially separated from employment on or after May 18, 2008, through December 10, 2011, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 8th day of April, 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8884 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,319]

La-Z-Boy Casegoods, Inc.—LEA Also Known as American Drew Wilkesboro, NC; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (“Act”), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to apply for Worker Adjustment Assistance on March 19th, 2010 applicable to workers of La-Z-Boy Casegoods, Inc.-LEA, also known as American Drew, Wilkesboro, North Carolina. The notice will be published in the **Federal Register** soon.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of home furniture.

The review shows that on February 25, 2008, a certification of eligibility to apply for adjustment assistance was issued for all workers of La-Z-Boy Greensboro, Inc., North Wilkesboro, North Carolina, separated from employment on or after October 29, 2007 through February 25, 2010. The notice was published in the **Federal Register** on March 11, 2008 (73 FR 13017).

In order to avoid an overlap in worker group coverage, the Department is amending the January 8, 2009 impact date established for TA–W–73,319, to read February 26, 2010. The amended notice applicable to TA–W–73,319 is hereby issued as follows:

All workers of La-Z-Boy Casegoods, Inc.-LEA, also known as American Drew, Wilkesboro, North Carolina, who became totally or partially separated from employment on or after February 26, 2010, through March 19, 2012, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 8th day of April 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8879 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–72,565]

Robert Bosch LLC, Including On-Site Leased Workers From Bosch Management Services North America, South Haven Community Hospital, Huffmaster Inc., and Williamson Employment Services St. Joseph, MI; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (“Act”), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on February 24, 2010, applicable to workers of Robert Bosch

LLC, including on-site leased workers of Bosch Management Services North America, South Haven Community Hospital, Huffmaster Inc., and Williamson Employment Services, St. Joseph, Michigan. The notice will be published soon in the **Federal Register**.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of automotive brakes.

The review shows that on September 24, 2007, a certification of eligibility to apply for adjustment assistance was issued for all workers of Robert Bosch LLC, including on-site leased workers of Bosch Management Services North America, South Haven Community Hospital, Huffmaster Inc., and Williamson Employment Services, separated from employment on or after June 9, 2007 through November 28, 2009. The notice was published in the **Federal Register** on December 11, 2007 (72 FR 70345).

In order to avoid an overlap in worker group coverage, the Department is amending the September 16, 2008 impact date established for TA–W–72,565, to read November 29, 2009.

The amended notice applicable to TA–W–62,337 is hereby issued as follows:

All workers of Robert Bosch LLC, including on-site leased workers of Bosch Management Services North America, South Haven Community Hospital, Huffmaster Inc., and Williamson Employment Services, who became totally or partially separated from employment on or after November 29, 2009, through February 24, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 31st day of March 2010.

Michael W. Jaffe

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8877 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–72,241]

Autodie, LLC Including On-Site and Off-Site Individual Contractors Grand Rapids, MI; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (“Act”), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on March 3, 2010, applicable to workers of Autodie, LLC, including on-site and off-site individual contractors, Grand Rapids, Michigan. The notice will be published soon in the **Federal Register.**

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of metal forming dies for automobiles and automobile components.

The review shows that on September 24, 2007, a certification of eligibility to apply for adjustment assistance was issued for all workers of Autodie, LLC, Grand Rapids, Michigan, separated from employment on or after July 30, 2007 through September 24, 2009. The notice was published in the **Federal Register** on October 12, 2007 (72 FR 58131).

In order to avoid an overlap in worker group coverage, the Department is amending the August 31, 2008 impact date established for TA–W–72,241, to read September 25, 2009.

The amended notice applicable to TA–W–72,241 is hereby issued as follows:

All workers of Autodie, LLC, including on-site and off-site individual contractors, Grand Rapids, Michigan, who became totally or partially separated from employment on or after September 25, 2009, through March 3, 2012, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 30th day of March, 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8876 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–62,220]

Agrium U.S., Inc., Kenai Nitrogen Operation, Including On-Site Leased Workers From NMS (Nana Management Systems) and Heat & Frost Insulation, Inc., Kenai, AK; Amended Notice of Revised Determination on Reconsideration

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 Notice of Revised Determination on Reconsideration on January 8, 2008. The notice was published in the **Federal Register** on January 16, 2008 (73 FR 2946). The Revised Determination was amended on October 22, 2008 to include on-site leased workers from NMS (Nana Management Systems). The notice was published in the **Federal Register** on November 3, 2008 (73 FR 65410–65411)

At the request of the petitioner, the Department reviewed the Notice of Revised Determination on Reconsideration for workers of the subject firm. The workers are engaged in the production of anhydrous ammonia and urea.

New information shows that workers leased workers from Heat & Frost Insulation, Inc. were employed on-site at the Kenai, Alaska location of Agrium U.S., Inc., Kenai Nitrogen Operation. The Department has determined that these workers were sufficiently under the control of Agrium U.S., Inc., Kenai Nitrogen Operation to be considered leased workers.

Based on these findings, the Department is amending this revised determination to include workers leased from Heat & Frost Insulation, Inc. working on-site at the Kenai, Alaska location of the subject firm.

The intent of the Department’s certification is to include all workers employed at Agrium U.S., Inc., Kenai Nitrogen Operation, Kenai, Alaska who were adversely affected by a shift in production of anhydrous ammonia and urea to Damietta, Egypt.

The amended notice applicable to TA–W–62,220 is hereby issued as follows:

All workers of Agrium U.S., Inc., Kenai Nitrogen Operation, including on-site leased workers from NMS (Nana Management Systems) and Heat & Frost Insulation, Inc., Kenai, Alaska, who became totally or partially separated from employment on or after April 13, 2007, through January 8, 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 22nd day of January 2010.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8868 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than April 29, 2010.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than April 29, 2010.

The petitions filed in this case are available for inspection at the Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 7th day of April 2010.

Elliott Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

APPENDIX

[TAA Petitions Instituted between 3/8/10 and 3/12/10]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
73651	File-EZ Folder, Inc. (Comp)	Spokane, WA	03/08/10	03/05/10
73652	Robert Bosch, LLC (State)	Plymouth, MI	03/08/10	02/10/10
73653	Heartland Companies, Ltd. (Wkrs)	San Francisco, CA	03/08/10	02/10/10
73654	Bose Corporation (State)	Framingham, MA	03/08/10	03/01/10
73655	Camson Pipe Company (Wkrs)	Erie, PA	03/08/10	03/05/10
73656	JK Products and Services, Inc. (Wkrs)	Jonesboro, AR	03/08/10	03/05/10
73657	SunGard Public Sector (Comp)	Lake Mary, FL	03/08/10	03/05/10
73658	Arrow Truck Sales (State)	Montebello, CA	03/08/10	02/16/10
73659	Meridian Enterprises Corporation (Wkrs)	Hazelwood, MO	03/08/10	03/01/10
73660	iLevel by Weyerhaeuser (Comp)	Boise, ID	03/09/10	03/08/10
73661	Maersk Agency USA, Inc. (Wkrs)	Charlotte, NC	03/09/10	03/01/10
73662	Saxon (State)	Elk River, MN	03/09/10	01/06/10
73663	Appleton Papers, Inc. (Comp)	Appleton, WI	03/09/10	03/08/10
73664	Coloplast US Headquarters (State)	Vadwais Heights, MN	03/09/10	03/08/10
73665	Peek Traffic Corporation (Wkrs)	Bedford, PA	03/09/10	03/08/10
73666	Badger Meter, Inc. (Comp)	Milwaukee, WI	03/09/10	02/22/10
73667	Saint-Gobain Performance Plastics (Comp)	Bristol, RI	03/09/10	03/08/10
73668	Swets (State)	Runnemede, NJ	03/10/10	03/09/10
73669	Lazar Industries, LLC (Comp)	Siler City, NC	03/10/10	03/08/10
73670	Bimbo Bakeries USA (Comp)	Houston, TX	03/10/10	01/28/10
73671	Vygon US, LLC (Comp)	Valley Forge, PA	03/10/10	02/26/10
73672	Continental Automotive Systems, Inc. (Comp)	Elma, NY	03/10/10	03/09/10
73673	General Motors Corporation (Comp)	Detroit, MI	03/10/10	03/08/10
73674	E. W. Daniel Company (USW)	Cleveland, OH	03/10/10	02/11/10
73675	Franklin Templeton Investments Company, LLC (Wkrs)	San Mateo, CA	03/10/10	02/24/10
73676	Adria Healthcare (Wkrs)	Irving, TX	03/10/10	03/08/10
73677	Robert Busch, LLC (State)	Plymouth, MI	03/10/10	02/10/10
73678	New United Motor Manufacturing, Inc. (Comp)	Fremont, CA	03/10/10	02/22/10
73679	Liz Claiborne, Inc. (Wkrs)	North Bergen, NJ	03/10/10	02/18/10
73680	Bleden (Hirschmann Automation and Controls) (Wkrs)	Chambersburg, PA	03/10/10	03/01/10
73681	Grant Products International (Wkrs)	Brownsville, TX	03/11/10	03/10/10
73682	Hartford Financial Services Group, Inc. (State)	Aurora, IL	03/11/10	03/10/10
73683	Contour Aerospace—A Vought Company (Comp)	Everett, WA	03/11/10	03/10/10
73684	Graphic Packaging (Wkrs)	Lawrenceburg, TN	03/11/10	02/17/10
73685	Northwestern Precision Manufacturing (Wkrs)	Vernon Hills, IL	03/11/10	03/10/10
73686	MWH Americas (Human Resources (Wkrs)	Broomfield, CO	03/11/10	03/03/10
73687	Somerset Plastics, Inc. (Comp)	Somerset, PA	03/11/10	03/05/10
73688	Double AA Parking and Trucking, Inc. (Wkrs)	Calexico, CA	03/11/10	03/05/10
73689	General Motors Component Holdings, LLC (Comp)	Kokomo, IN	03/11/10	03/08/10
73690	LSI Industries, Inc. (Comp)	Cincinnati, OH	03/11/10	03/05/10
73691	R. E. Phelon Company, Inc. (Rep)	Aiken, SC	03/11/10	03/10/10
73692	Perot Systems (Dell) (Wkrs)	Plano, TX	03/11/10	02/27/10
73693	Sony Ericsson, USA (Wkrs)	RTP, NC	03/11/10	02/15/10

APPENDIX—Continued

[TAA Petitions Instituted between 3/8/10 and 3/12/10]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
73694	Travelers Indemnity Company (Wkrs)	Hartford, CT	03/11/10	03/08/10
73695	Woodland Mills (Wkrs)	Mill Spring, NC	03/11/10	03/10/10
73696	Deloitte FAS LLP (State)	Houston, TX	03/11/10	05/27/09
73697	Federal Coach (Wkrs)	Fort Smith, AR	03/12/10	03/12/10
73698	Holloway Sportswear Inc. (Wkrs)	Jackson Center, OH	03/12/10	03/01/10
73699	ABM Janitorial (Wkrs)	Fremont, CA	03/12/10	03/11/10
73700	Roche Diagnostics Operations, Centralized Diagnostics (Wkrs).	Indianapolis, IN	03/12/10	03/11/10
73701	Acuity Brands Lighting (Comp)	Cochran, GA	03/12/10	03/11/10
73702	Komatsu Latin America (Wkrs)	Miami, FL	03/12/10	03/11/10

[FR Doc. 2010–8866 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility to Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than April 29, 2010.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than April 29, 2010.

The petitions filed in this case are available for inspection at the Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 7th day of April 2010.

Elliott Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

Appendix

TAA petitions instituted between 3/15/10 and 3/19/10

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
73703	Betts, USA (Wkrs)	Florence, KY	03/15/10	01/19/10
73704	Qantas Airways Ltd (Wkrs)	Los Angeles, CA	03/15/10	03/12/10
73705	Lap Tech Industries (Wkrs)	Dayton, OH	03/15/10	03/12/10
73706	Blumental Printworks (Wkrs)	New Orleans, LA	03/15/10	03/11/10
73707	JD Norman Industries, Inc. (Comp)	Brooklyn, OH	03/15/10	03/12/10
73708	Hayden Twist Drill (Wkrs)	Warren, MI	03/15/10	03/05/10
73709	Kurrmi, Inc. (Wkrs)	New York, NY	03/15/10	03/01/10
73710	Sam Malone Enterprises, Inc. (Wkrs)	City of Industry, CA	03/15/10	03/11/10
73711	Air Products and Chemicals, Inc. (Wkrs)	Allentown, PA	03/16/10	03/05/10
73712	Fiserv Fulfillment Services, Inc. (Rep)	St. Louis Park, MN	03/16/10	03/10/10
73713	General Electric (Comp)	Euclid, OH	03/16/10	03/03/10
73714	Interscope Manufacturing, Inc. (Wkrs)	Middletown, OH	03/16/10	03/09/10
73715	Axiant, LLC (Wkrs)	Huntersville, NC	03/16/10	02/16/10
73716	Kmart (Sears holding Corp) (Comp)	Huber Heights, OH	03/17/10	03/10/10
73717	Aperto Networks Inc. (Wkrs)	Milpitas, CA	03/17/10	03/15/10
73718	Medica (STATE)	Minnesota, MN	03/17/10	03/16/10
73719	Franklin Disposables LP (Wkrs)	Columbus, OH	03/17/10	03/16/10
73720	Apria Health Care (Wkrs)	Irving, TX	03/17/10	03/15/10
73721	RCL Burco, Inc. (COMP)	Culloden, WV	03/17/10	03/16/10
73722	Sojitz Corporation of America (ONE–ST)	Seattle, WA	03/17/10	03/15/10
73723	First Solutions (STATE)	Duluth, MN	03/17/10	03/16/10
73724	Rhinestahl Corporation (STATE)	Cincinnati, OH	03/17/10	03/15/10
73725	Michaels (Wkrs)	Irving, TX	03/17/10	03/10/10
73726	Pentair Water (COMP)	Ashland, OH	03/17/10	03/04/10
73727	The Berry Company (COMP)	Honolulu, HI 968813, HI	03/17/10	03/10/10
73728	The Berry Company (COMP)	St. Peters, MO	03/17/10	03/10/10
73729	The Berry Company, LLC (LIYP) (COMP)	La Crosse, WI	03/17/10	03/10/10

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
73730	The Berry Company, LLC (LIYP) (COMP)	Federal Way, WA	03/17/10	03/10/10
73731	The Berry Company, LLC (LIYP) (Comp)	Erie, PA	03/17/10	03/10/10
73732	The Berry Company, LLC (LIYP) (COMP)	Rochester, NY	03/17/10	03/10/10
73733	The Berry Company, LLC (LIYP) (COMP)	Matthews, NC	03/17/10	03/10/10
73734	Purchasingnet, Inc. (Wkrs)	Austin, TX	03/17/10	03/16/10
73735	Product Action (ONE–ST)	Dayton, OH	03/17/10	03/05/10
73736	Toyota engineering and Manufacturing North America Team (TEMA) (State).	Fremont, CA	03/18/10	03/17/10
73737	Cullman Casting Corporation (State)	Cullman, AL	03/18/10	03/17/10
73738	Allied Systems, Ltd. (Comp)	Atlanta, GA	03/18/10	03/17/10
73739	World Wide Technology (Wkrs)	St. Louis, MO	03/18/10	03/17/10
73740	Allstate Insurance Company (State)	Northbrook, IL	03/18/10	03/12/10
73741	Kenco/Komptsu America (State)	Lexington, KY	03/18/10	03/16/10
73742	Covidien (Comp)	Oriskany Falls, NY	03/18/10	03/17/10
73743	American Fiber and Finishing, Inc. (Comp)	Allemarte, NC	03/18/10	03/17/10
73744	Sony Ericsson, USA (Wkrs)	Research Triangle Park, NC	03/18/10	02/15/10
73745	Zumtobel Lighting Inc. (UAW)	Garfield, NJ	03/19/10	03/17/10
73746	Price Water House Coopers LLP (Wkrs)	New York, NY	03/19/10	03/17/10
73747	Payroll Solutions/Synergy (Wkrs)	North Las Vegas, NV	03/19/10	03/17/10
73748	Commercial Construction Management and Resource (STATE).	Milford, OH	03/19/10	03/09/10
73749	Assembly and Test Worldwide, Inc. (STATE)	Shelton, CT	03/19/10	03/17/10
73750	General Motors Corporation (Wkrs)	Detroit, MI	03/19/10	03/08/10
73751	RHealth, LLC (STATE)	Memphis, TN	03/19/10	03/17/10
73752	Industrial Metal Products Corp. (STATE)	Lansing, MI	03/19/10	03/17/10

[FR Doc. 2010–8867 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–65,433]

American Racing Equipment, LLC, Denver, CO; Notice of Negative Determination on Remand

On January 8, 2010, the United States Court of International Trade (USCIT) granted the Department of Labor's request for voluntary remand to conduct further investigation in *Former Employees of American Racing Equipment, LLC* v. *United States Secretary of Labor* (Court No. 09–00288).

On April 6, 2009, the Department of Labor (Department) issued a Negative Determination regarding eligibility to apply for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA) applicable to workers and former workers of American Racing Equipment, LLC, Denver, Colorado (the subject firm). (AR 49) The Department's Notice of negative determination was published in the **Federal Register** on June 25, 2009 (74 FR 3033). (AR 59.) The determination stated that the subject firm's affiliate did not import two piece wheels like or directly competitive with those warehoused and wholesaled by the subject worker group. Additionally, the customers of the affiliate did not make import purchases of these articles in the period under investigation. (AR 50.)

By application dated April 25, 2009, the petitioner requested administrative reconsideration on the Department's negative determination. In the request for reconsideration, the petitioner alleged that the workers of the subject firm supported production of cast, one piece wheels and that the subject firm shifted production of these articles abroad and increased imports of these products. (AR 61–73.)

Because new information was provided by the petitioners that had not been previously considered, the Department issued a Notice of Affirmative Determination Regarding Application for Reconsideration for workers at the subject firm on May 11, 2009. (AR 76.) The Notice was published in the **Federal Register** on June 16, 2009 (74 FR 28552). (AR 79.)

In the request for reconsideration, the petitioner alleged that the workers of the subject firm supported production of cast, one piece wheels, that the subject firm shifted production of the cast, one piece wheels abroad, and that there was an increase in imports of these articles. (AR 62–64, 68–70.)

During the reconsideration investigation, the Department obtained additional information from the company official regarding the petitioners' claims. The additional material, however, did not contain information sufficient to reverse the initial negative determination.

As a result of the reconsideration investigation, the Department issued a Notice of Negative Determination Regarding Application for Reconsideration on June 26, 2009. (AR 83–85) The determination stated that the Department did not find additional information pertaining to a shift in production or increased imports that contributed to the petitioners' separations. (AR 84, 85) On July 14, 2009, the Notice was published in the **Federal Register** (74 FR 34044). (AR 87, 88.)

In a letter to the Colorado Department of Labor, dated July 23, 2009, the Plaintiff appealed to the USCIT for judicial review. The Plaintiff stated that "the relevant period" for the investigation should have been identical to the relevant time period covered in TAA certifications TA–W–58,665 and TA–W–63,760 and based the appeal on "facts not considered" and misinterpretation of the facts.

On December 14, 2009, the Department requested the USCIT to grant its request for remand to investigate further the Plaintiffs' allegations. On January 8, 2010, the USCIT granted the Department's Motion for voluntary remand.

On May 18, 2009, the Department implemented the Trade and Globalization Adjustment Assistance

Act of 2009 (TGAAA). Under Section 1891(a) of the TGAAA, only worker groups covered by petitions filed on or after May 18, 2009 are eligible to apply for TAA under provisions set forth in the TGAAA. Worker groups covered by petitions filed before May 18, 2009 must meet the eligibility criteria that existed at the time the petition was filed. Because the petition for TA–W–65,433 was filed on February 26, 2009, in order for the subject worker group to be eligible to apply for TAA as primary workers (workers of a firm that produces an article), the workers must meet the group eligibility requirements under Section 222(a) of the Trade Act of 1974, as amended, which existed on February 26, 2009.

The group eligibility requirements under Section 222(a) of the Trade Act which existed on February 26, 2009 can be satisfied in one of two ways:

I. Section (a)(2)(A)—

A. 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; *and*

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; *and*

C. 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;

or

II. Section (a)(2)(B)—

A. 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; *and*

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; *and*

C. One of the Following Must be Satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States; *or*

2. The country to which the workers' firm has shifted production of the articles is a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; *or*

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

In order to determine whether the subject workers meet the TAA group eligibility requirements, the Department must first determine whether or not an article was produced at the subject firm, then determine whether the workers are adversely impacted by increased imports of articles like or directly competitive with those produced by the subject firm or by a shift in production abroad of articles like or directly competitive with those which are produced by the subject firm.

It is the Department's policy that in order for petitioners to qualify for TAA as primary workers, they must be (1) engaged in domestic production; or (2) be in support of an affiliated domestic production facility; or (3) under the control of an unaffiliated company that produces the article that the subject workers support. Where the workers support production, the facility that they support must be import-impacted or have shifted to a country identified under Section 113 of the Trade Adjustment Assistance Reform Act of 2002 (Pub. L. 107–210).

In conducting the remand investigation, the Department obtained additional information from the subject firm, SAR 89–90, 99–100, 111–113, and solicited input from the Plaintiff. SAR 91. Based on the information collected, SAR 99–100, 107–110, 111–113, the Department determined that the worker group at the subject firm providing services such as warehousing and wholesaling of wheels was not in direct support of the production of these articles and, therefore, does not meet the test of being engaged in the production of an article for the purposes of the Trade Act.

The Department's policy is to provide TAA benefits to workers covered by a petition filed before May 18, 2009, who work in a facility of the workers' firm (the "appropriate subdivision" identified in the petition) that supports an import-impacted domestic production facility of the workers' firm. 29 CFR Section 90.11(c)(7) requires that the petition includes a "description of the articles produced by the workers' firm or appropriate subdivision, the production or sales of which are adversely affected by increased imports, and a description of the imported articles concerned." Further, 29 CFR Section 90.2 describes an appropriate subdivision as "an establishment in a multi-establishment firm which produces the domestic article in question" and includes "auxiliary facilities operated in conjunction with (whether or not physically separate from) production facilities."

The Plaintiffs allege that they were impacted by increased imports of wheels following a shift in production abroad from the subject firm's production facility located in Rancho Dominquez, California. The remand investigation revealed that the worker group at the Denver, Colorado facility did not support the production at the Rancho Dominguez, California location. Rather, the majority of the product warehoused and wholesaled by the Denver, Colorado worker group was imported from China and a small portion entered the Denver, Colorado facility as a finished article from the subject firm facility in Kansas City, Missouri. The remand investigation also revealed that the worker group at the Denver, Colorado location was not engaged in the assembly or finishing of the articles warehoused and wholesaled out of that location. Furthermore, when the Denver, Colorado facility ceased to operate in May 2008, the work was consolidated domestically. SAR 99–100, 107–110, 111–113.

The Plaintiffs also allege that they were impacted by the shift in production abroad and subsequent imports. The worker group at the Denver, Colorado facility did not support the production at the Rancho Dominguez, California facility nor did they support production at any other domestic or affiliated facility of the subject firm. SAR 99–100, 107–110, 111–113.

Additionally, the Plaintiffs allege that the period under investigation should be the same as the period used for the TAA certifications of petitions TA–W–58,665 and TA–W–63,760. The period of the investigation is determined by the date of filing of the petition. *See, e.g.,* 29 CFR 90.2 "increased imports" definition identifying the representative base period. During the relevant period of investigation for the subject petition, however, the Denver, Colorado facility did not support production at the Rancho Dominguez, California facility, nor was the product manufactured at the Rancho Dominguez, California facility sold out of the Denver, Colorado location. SAR 99–100, 107–110, 111–113.

The Department determined that the subject workers are not engaged in the production of an article or in support of an affiliated, domestic production facility. As such, the Department determines that there was no "shift in production by such workers' firm or subdivision to a foreign country" as required by the Trade Act. Because the workers did not produce an article, and did not support a firm or appropriate subdivision that produced an article domestically, the workers cannot be considered import impacted or affected by a shift of production abroad.

In order for the Department to issue a certification of eligibility to apply for ATAA, the subject worker group must be certified eligible to apply for TAA. Since the subject workers are denied eligibility to apply for TAA, the workers cannot be certified eligible for ATAA.

Conclusion

After careful reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of American Racing Equipment, LLC, Denver, Colorado.

Signed at Washington, DC, this 8th day of April, 2010.

Del Min Amy Chen

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8870 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,634]

Yale Industrial Trucks-PGH, Inc. Monroeville, PA; Notice of Negative Determination Regarding Application for Reconsideration

By application received March 16, 2010, a petitioner requested administrative reconsideration of the Department's negative determination regarding eligibility to apply for Trade Adjustment Assistance (TAA), applicable to workers and former workers of the subject firm. The Department's Notice of determination was issued on March 3, 2010 and will soon be published in the **Federal Register.**

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The negative determination of the TAA petition filed on behalf of workers at Yale Industrial Trucks-PGH, Inc., Monroeville, Pennsylvania, was based on the findings that: The subject firm had not shifted abroad forklift truck sales and maintenance services or imported forklift truck sales and maintenance services during the relevant period; the declining customers of the subject firm had not obtained truck sales and maintenance services from foreign firms during the relevant period; and the workers did not produce an article or supply a service that was used by a firm with TAA-certified workers in the production of an article or supply of a service that was the basis for TAA-certification.

The petitioner stated that the workers of the subject firm should be eligible for TAA because some of that firm's largest customers, who are TAA-certified, have cut back production in some plants and shut down production at other plants because of foreign steel imports and have consequently sent back a large number of the fork lift trucks leased and serviced by the subject firm. Moreover, the petitioner alleged that there were many fork lift truck companies selling foreign-made fork lift trucks.

The initial investigation revealed that the secondary certification that the petitioner is seeking is not possible because the subject firm provided tools and related services used in production but not component parts, as required by Section 222(d) of the Act, 19 U.S.C. 2272(d).

Furthermore, during the initial investigation the Department surveyed the subject firm's major declining customers regarding their purchases of forklift trucks and maintenance services during the relevant period. The survey revealed no imports of forklift trucks or related maintenance services.

The petitioner did not supply facts not previously considered; nor provide additional documentation indicating that there was either (1) a mistake in the determination of facts not previously considered or (2) a misinterpretation of facts or of the law justifying reconsideration of the initial determination.

After careful review of the request for reconsideration, the Department determines that 29 CFR 90.18(c) has not been met.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed in Washington, DC, this 1st day of April, 2010.

Del Min Amy Chen,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8874 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–72,103]

Terex USA, LLC, Cedar Rapids, IA; Notice of Negative Determination Regarding Application for Reconsideration

By application dated March 8, 2010, the State of Iowa Trade Adjustment Assistance (TAA) Coordinator requested administrative reconsideration of the Department's negative determination regarding eligibility to apply for TAA applicable to workers and former workers of the subject firm. The Notice of negative determination was signed on February 3, 2010. The Department's Notice was published in the **Federal Register** on March 12, 2010 (74 FR 11925).

The petitioner states in the request for reconsideration that the initial customer survey was limited to only the largest customer of the subject firm and that perhaps many of the subject firm's customers are purchasing imports of products like those produced by the subject firm, and that such purchasing of imports by many small customers could have brought about the worker separations at the subject firm.

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The initial investigation resulted in a negative determination, which was based on the finding that shifts of production of crushing, screening, and paving equipment (types of construction equipment) did not contribute importantly to worker separations at the subject firm and that a major portion of the sales decline of the subject firm can

be attributed to a loss of exports and thus is not affected by imports.

During the initial investigation, the subject firm provided sales and contact information for its major declining customers: one domestic customer and three foreign customers. The sole domestic customer constituted 16 percent of the sales decline experienced by the subject firm and the three foreign customers constituted 72 percent of the subject firm's sales decline.

The Department confirmed during the initial investigation that the three foreign customers were purchasing finished articles and not component parts of construction equipment from the subject firm, and determined that the subject firm's declining sales with the three foreign customers was loss of export business by the subject firm. Further, during the initial investigation, the Department had collected aggregate data that shows that imports into the United States of agricultural and construction machinery decreased by almost 40 percent during the relevant period.

Because the export losses and the losses to the sole domestic customer account for 88 percent of the decline in sales for the subject firm and there were decreasing aggregate imports of construction equipment, the Department determined that the customer survey conducted during the initial investigation was appropriate.

The petitioner did not supply facts not previously considered; nor provide additional documentation indicating that there was either (1) a mistake in the determination of facts not previously considered or (2) a misinterpretation of facts or of the law justifying reconsideration of the initial determination.

After careful review of the request for reconsideration, the Department determines that 29 CFR 90.18(c) has not been met.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed in Washington, DC this 1st day of April 2010.

Del Min Amy Chen,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 2010–8875 Filed 4–16–10; 8:45 am]

BILLING CODE 4510–FN–P

OFFICE OF MANAGEMENT AND BUDGET

Work Reserved for Performance by Federal Government Employees; Correction

AGENCY: Office of Federal Procurement Policy, Office of Management and Budget.

ACTION: Notice; Correction.

SUMMARY: The Office of Federal Procurement Policy (OFPP) in the Office of Management and Budget (OMB) is making corrections to the addresses and instructions for submitting and viewing public comments on the Proposed Policy Letter "Work Reserved for Performance by Federal Government Employees" (75 FR 16188–16197, March 31, 2010). The **ADDRESSES** section and updated Web site below should be used in place of those previously published in the March 31, 2010 notice. All other information from the March 31st notice, including the June 1, 2010, deadline for submission of comments, remains unchanged. The full text of the original notice is available at *http://edocket.access.gpo.gov/2010/2010–7329.htm.*

FOR FURTHER INFORMATION CONTACT: Mathew Blum, OFPP, (202) 395–4953 or *mblum@omb.eop.gov.*

Corrections

In the **Federal Register** on March 31, 2010, beginning at the top of page 16189, correct the **ADDRESSES** to read:

ADDRESSES: All comments should be submitted via one of the following methods:

- *Online: http://www.regulations.gov.*
- *Fax:* 202–395–5105.
- *Mail:* Office of Federal Procurement Policy, *Attn:* Mathew Blum, New Executive Office Building, Room 9013, 725 17th Street, NW., Washington, DC 20503.
- *Instructions:* Please submit comments only and include your name, company name (if any), and cite "Proposed OFPP Policy Letter" in all correspondence. All comments received will be posted, without change, to *http://www.regulations.gov,* without redaction, so commenters should not include information that they do not wish to be posted (for example because they consider it personal or business confidential).

In the **Federal Register** on March 31, 2010, correct the hyperlink in the last sentence on page 16189 to read:

For a copy of public comments, go to *http://www.whitehouse.gov/omb/assets/procurement_gov_contracting/public_comments.pdf.*

Daniel I. Gordon,

Administrator, Office of Federal Procurement Policy.

[FR Doc. 2010–8824 Filed 4–16–10; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

Advisory Committee On Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee On Plant License Renewal

The ACRS Subcommittee on Plant License Renewal will hold a meeting on May 5, 2010, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, May 5, 2010—8:30 a.m. until 12 p.m.

The Subcommittee will discuss the Cooper Nuclear Station License Renewal Application and the associated Safety Evaluation Report (SER) with Open Items prepared by the staff. The Subcommittee will hear presentations by and hold discussions with representatives of the NRC staff, Nebraska Public Power District, and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Mrs. Kathy Weaver (Telephone 301–415–6236 or E-mail *Kathy.Weaver@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least 30 minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal**

Register on October 14, 2009, (74 FR 52829).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

Dated: *April 8, 2010.*

Antonio Dias,

Chief, Reactor Safety Branch A, Advisory Committee on Reactor Safeguards.

[FR Doc. 2010–8914 Filed 4–16–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Planning and Procedures

The ACRS Subcommittee on Planning and Procedures will hold a meeting on May 5, 2010, in Room T–2B1, at 11545 Rockville Pike, Rockville, MD.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, May 5, 2010, 12:00 p.m.–1 p.m.

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Mr. Peter Wen (Telephone 301–415–2832 or E-mail: *Peter.Wen@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least 30 minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 14, 2010, (74 FR 58268–58269).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

Date: *April 8, 2010.*

Antonio Dias,

Chief, Reactor Safety Branch A, Advisory Committee on Reactor Safeguards.

[FR Doc. 2010–8920 Filed 4–16–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on AP1000; Notice of Meeting

The ACRS Subcommittee on the AP1000 will hold a meeting on April 22, 2010, at 11545 Rockville Pike, Room T2–B1, Rockville, Maryland.

Part of the meeting will be open to public attendance and the other part will be closed to protect unclassified safeguards information or information that is proprietary to Westinghouse Electric Company and its contractors, pursuant to 5 U.S.C. 552b(c)(3) and (4).

The proposed agenda for the subject meeting is as follows:

Thursday, April 22, 2010—8:30 a.m.–5 p.m.

The Subcommittee will be briefed by NuStart and the NRC staff on the subject of Loss of Large Areas due to Fire/Explosions, and by Westinghouse on the subject of Shield Building Design. Westinghouse will also address issues associated with previous AP1000 Subcommittee meetings. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Mr. Weidong Wang, (Telephone 301–415–6279, E-mail: *Weidong.Wang@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be e-mailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least 30 minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 14, 2009 (74 FR 58268–58269).

Detailed ACRS meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs/.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in major inconvenience.

Dated: April 8, 2010.

Antonio F. Dias,

Chief, Reactor Safety Branch B, Advisory Committee on Reactor Safeguards.

[FR Doc. 2010–8916 Filed 4–16–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2009–0418]

Notice of Issuance of Regulatory Guide

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Issuance and Availability of Regulatory Guide 6.9, Revision 1, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material."

FOR FURTHER INFORMATION CONTACT: Jack W. Foster, Licensing Branch, Licensing and Inspection Support Directorate, Division of Materials Safety and State Agreement, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6250 or e-mail *Jack.Foster@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing a revision to an existing guide in the agency's "Regulatory Guide" series. This series was developed to describe and make available to the public information such as methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

Revision 1 of Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," was issued with a temporary identification as Draft Regulatory Guide, DG–6007. This regulatory guide directs the reader to the type of quality assurance (QA) and quality control (QC) program acceptable to the staff of the NRC during the review of an application to manufacture or distribute sealed sources and devices containing byproduct materials.

II. Further Information

In September 2009, DG–6007 was published with a public comment period of 60 days from the issuance of the guide. No comments were received and the public comment period closed on November 21, 2009. Electronic copies of Regulatory Guide 6.9, Revision 1 are available through the NRC's public Web site under "Regulatory Guides" at *http://www.nrc.gov/reading-rm/doc-collections/.*

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR) located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555–0001. The PDR can also be reached by telephone at (301) 415–4737 or (800) 397–4205, by fax at (301) 415–3548, and by e-mail to *pdr.resource@nrc.gov.*

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

Dated at Rockville, Maryland, this 12th day of April 2010.

For the Nuclear Regulatory Commission.

Andrea D. Valentin,

Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2010–8922 Filed 4–16–10; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Declaration for Federal Employment, OF 306, 3206–0182

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day Notice and request for comments.

SUMMARY: Federal Investigative Services (FIS), U.S. Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on an expiring information collection request (ICR), Office of Management and Budget (OMB) Control No. 3206–0182, for the Declaration for Federal Employment, Optional Form (OF) 306. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. The Office of Management and Budget (OMB) is particularly interested in comments that:

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, 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 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.

DATES: Comments are encouraged and will be accepted until June 18, 2010. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to FIS, OPM, 1900 E Street, NW., Washington, DC 20415, *Attention:* Lisa Loss or sent via electronic mail to *FISDFormsComments@opm.gov*.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting FIS, OPM, 1900 E Street, NW., Washington, DC 20503, Attention: Lisa Loss or sent via electronic mail to *FISDFormsComments@opm.gov.*

SUPPLEMENTARY INFORMATION: The Declaration for Federal Employment Optional Form (OF) 306, is completed by applicants who are under consideration for Federal or Federal contract employment. The OF 306 requests that the applicant provide personal identifying data, including convictions, imprisonments, probations, paroles or military court martial in the past 10 years, delinquency on a Federal debt, Selective Service Registration, United States military service and Federal civilian or military retirement pay or pension received or applied for. It is estimated that 178,114 individuals will respond annually. Each form takes approximately 15 minutes to complete. The annual estimated burden is 44,529 hours.

U.S. Office of Personnel Management.

John Berry,

Director.

[FR Doc. 2010–8955 Filed 4–16–10; 8:45 am]

BILLING CODE 6325–53–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Federal Cyber Service: Scholarship for Service (SFS) Registration Web Site

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day Notice and request for comments.

SUMMARY: The Human Resources Solutions, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an existing information collection request (ICR) 3206–0246, SFS Registration. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. The Office of Management and Budget is particularly interested in comments that:

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, 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 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.

DATES: Comments are encouraged and will be accepted until June 18, 2010. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to U.S. Office of Personnel Management, San Antonio Office, 8610 Broadway, Rm. 305, San Antonio, TX 78217, *Attention:* Kathryn Roberson or sent via electronic mail to: *sfs@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the San Antonio Services Branch, Office of Personnel Management, 8610 Broadway, Rm. 305, San Antonio, TX 78217, *Attention:* Kathryn Roberson or sent via electronic mail to: *sfs@opm.gov.*

SUPPLEMENTARY INFORMATION: The SFS Program was established by the National Science Foundation in accordance with the Federal Cyber Service Training and Education Initiative as described in the President's *National Plan for Information Systems Protection.* This program seeks to increase the number of qualified students entering the fields of information assurance and computer security in an effort to respond to the threat to the Federal Government's information technology infrastructure. The program provides selected 4-year colleges and universities scholarship grants to attract students to the information assurance field. Participating students who receive scholarships from this program are required to serve a 10-week internship during their studies and complete a post-graduation employment commitment equivalent to the length of the scholarship or one year, whichever is longer. Approval of the webpage is necessary to facilitate the timely registration, selection and placement of program-enrolled students in Federal agencies.

Analysis

Agency: Federal Cyber Service: Scholarship For Service Program, Office of Personnel Management.

Title: Scholarship For Service (SFS) Program Internet Site.

OMB Number: 3260–0246.

Frequency: Annually.

Affected Public: Individuals or Households.

Number of Respondents: 630.

Estimated Time per Respondent: 1 hour.

Total Burden Hours: 630 hours.

John Berry,

Director, Office of Personnel Management.

[FR Doc. 2010–8942 Filed 4–16–10; 8:45 am]

BILLING CODE 6325–38–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12096 and #12097]

West Virginia Disaster Number WV–00016

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of West Virginia (FEMA–1893–DR), dated 03/29/2010.

Incident: Severe Storms, Flooding, Mudslides, and Landslides.

Incident Period: 03/12/2010 and continuing through 04/09/2010.

Effective Date: 04/09/2010.

Physical Loan Application Deadline Date: 05/28/2010.

EIDL Loan Application Deadline Date: 12/29/2010.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of West Virginia, dated 03/29/2010 is hereby amended to establish the incident period for this disaster as beginning 03/12/2010 and continuing through 04/09/2010.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2010–8844 Filed 4–16–10; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12049 and #12050]

Maryland Disaster Number MD–00011

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of MARYLAND (FEMA–1875–DR), dated 02/19/2010.

Incident: Severe Winter Storm and Snowstorm

Incident Period: 12/18/2009 through 12/20/2009

DATES: *Effective Date:* 04/09/2010.

Physical Loan Application Deadline Date: 04/20/2010.

Economic Injury (EIDL) Loan Application Deadline Date: 11/19/2010.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration,

409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Maryland, dated 02/19/2010, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Anne Arundel, Charles, Talbot, and the Independent City of Baltimore.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2010–8848 Filed 4–16–10; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12102 and #12103]

West Virginia Disaster Number WV–00017

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of West Virginia (FEMA–1893–DR), dated 03/29/2010.

Incident: Severe Storms, Flooding, Mudslides and Landslides.

Incident Period: 03/12/2010 through 04/09/2010.

Effective Date: 04/09/2010.

Physical Loan Application Deadline Date: 05/28/2010.

Economic Injury (EIDL) Loan Application Deadline Date: 12/29/2010.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of West Virginia, dated 03/29/2010, is hereby amended to establish the incident period for this disaster as beginning 03/12/2010 and continuing through 04/09/2010.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2010–8845 Filed 4–16–10; 8:45 am]

BILLING CODE 8025–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61890; File No. SR–NYSEAmex–2010–31]

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing of Proposed Rule Change, and Amendment No. 1 Thereto, To Adopt, as a Pilot Program, a New NYSE Amex Equities Rule Series for the Trading of Securities Listed on the Nasdaq Stock Market Pursuant to a Grant of Unlisted Trading Privileges, and Amending Existing NYSE Amex Equities Rules as Needed To Accommodate the Trading of Nasdaq-Listed Securities on the Exchange

April 12, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 26, 2010, NYSE Amex LLC ("Exchange" or "NYSE Amex") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Exchange. Subsequently, on April 6, 2010, NYSE Amex filed Amendment No. 1 to the proposed rule change. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to (i) adopt, as a pilot program, a new NYSE Amex Equities Rule Series (Rules 500–525) for the trading of securities listed on the Nasdaq Stock Market ("Nasdaq") pursuant to a grant of unlisted trading privileges and (ii) amend existing NYSE Amex Equities Rules as needed to accommodate the trading of Nasdaq-listed securities on the Exchange. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to (i) adopt, as a pilot program, a new NYSE Amex Equities Rule Series (Rules 500–525) for the trading of Nasdaq-listed securities pursuant to a grant of unlisted trading privileges and (ii) amend existing NYSE Amex Equities Rules as needed to accommodate the trading of Nasdaq-listed securities on the Exchange.

Overview

As described in greater detail below, the Exchange proposes to adopt, as a pilot program, a new NYSE Amex Equities Rule Series to specifically govern the trading of any security listed on the Nasdaq that (i) is designated as an "eligible security" under the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis, as amended ("UTP Plan"),[3] and (ii) has been admitted to dealings on the Exchange pursuant to a grant of unlisted trading privileges in accordance with Section 12(f) of the Act,[4] (collectively, "Nasdaq Securities").[5] The Exchange

[3] *See* Securities Exchange Act Release No. 58863 (October 27, 2008), 73 FR 65417 (November 3, 2008) (notice of filing and immediate effectiveness of Amendment No. 20 to the UTP Plan). The Exchange's predecessor, the American Stock Exchange LLC, joined the UTP Plan in 2001. *See* Securities Exchange Act Release No. 55647 (April 19, 2007), 72 FR 2091 (April 27, 2007) (S7–24–89). In March 2009, the Exchange changed its name to NYSE Amex LLC. *See* Securities Exchange Act Release No. 59575 (March 13, 2009), 74 FR 11803 (March 19, 2009) (SR–NYSEALTR–2009–24). *See also* proposed Rule 501—NYSE Amex Equities.

[4] 15 U.S.C. 78l.

[5] As proposed, Nasdaq Securities shall be included within the definition of "security" as that term is defined in Rule 3—NYSE Amex Equities

Continued

also proposes to amend existing NYSE Amex Equities Rules as needed to accommodate the trading of Nasdaq Securities on the Exchange. The Exchange proposes that this pilot program commence on the date the proposed Rules are approved by the Commission [6] and that it continue until the earlier of the Commission's approval to make such pilot program permanent or September 30, 2010.[7]

In summary, the Exchange proposes to trade Nasdaq Securities on the same systems and facilities it uses to trade its listed securities in accordance with the same trading rules, subject to several key differences:

- There will not be an opening or closing auction for Nasdaq Securities traded on the Exchange. Trading in Nasdaq Securities will open on a quote at 9:30 a.m. and will close at 4 p.m., or immediately thereafter under certain circumstances, using the last sale on the Exchange as the Closing Price (defined below).
- "Good 'til Canceled" ("GTC") Orders and "Stop" Orders for Nasdaq Securities will be modified to provide that any GTC or Stop Orders that are unexecuted at the close of trading will be treated as Day Orders and canceled. In addition, the Exchange will not accept limit or market "At the Close" ("MOC/LOC"), "At the Opening" ("OPG"), "Closing Offset" ("CO") or "Good 'til Cross" ("GTX") Orders for the trading of Nasdaq Securities. All other order types will be accepted.
- Each Nasdaq Security will be assigned one Designated Market Maker ("DMM") Unit, though the allocation process will be streamlined to follow the approach used by the Exchange for Supplemental Liquidity Providers ("SLPs") (*see* Rule 107B—NYSE Amex Equities).[8]
- For those Nasdaq Securities in which they are registered, DMM Units will be responsible for the affirmative obligation of maintaining a fair and orderly market in accordance with Exchange rules, subject to an enhanced quoting requirement and a phased-in implementation of Depth Guidelines to enable the Exchange to collect trading data adequate to calculate such guidelines.
- Nasdaq Securities will trade using different Liquidity Replenishment Point ("LRP") parameters.
- Trading in Nasdaq Securities will be subject to rules that are substantially similar to FINRA's "Manning Rule", rather than Rule 92—NYSE Amex Equities.
- The Exchange's audit trail rules, including Rules 123— and 132B—NYSE Amex Equities, will apply to the trading of Nasdaq Securities on the Exchange, except that, those members and member organizations that are also FINRA members and subject to FINRA's Rule 7400 Series ("Order Audit Trail System" or "OATS") will be exempt from Rules 123— and 132B—NYSE Amex Equities.

NYSE Amex will trade Nasdaq-listed equities and any other Nasdaq-listed security that trades like an equity security (*e.g.,* rights, warrants), and will also trade the Invesco PowerShares QQQ™ Exchange Traded Fund.[9]

The Exchange intends to commence implementation of the trading of Nasdaq Securities using a phased-in approach and to expand the program to eventually include all Nasdaq Securities.

Proposed NYSE Amex Equities Rule 500 Series [10]

The Exchange proposes to adopt a new series of NYSE Amex Equities Rules (Rules 500 to 525) to specifically govern the trading of Nasdaq Securities on the Exchange.

1. Proposed Rule 500—NYSE Amex Equities (Applicability)

The Exchange will trade Nasdaq Securities as it currently trades its listed securities, subject to some distinctions. Thus, the Exchange proposes to adopt Rule 500—NYSE Amex Equities to provide that the trading of Nasdaq Securities on the Exchange shall be governed by the Rule 500 Series and all other NYSE Amex Equities Rules, except to the extent they conflict with the Rule 500 Series, in which case the Rule 500 series will control. In addition, proposed Rule 500 provides that the Exchange's Disciplinary Rules 475, 476, 476A and 477 will also apply to the trading of Nasdaq Securities on the Exchange.

2. Proposed Rule 501—NYSE Amex Equities (Definitions)

Although Nasdaq Securities will trade primarily in accord with existing NYSE Amex Equities Rules, the Exchange proposes to adopt Rule 501—NYSE Amex Equities to define key terms for the trading of Nasdaq Securities on the Exchange. All other terms will have the meanings assigned to them in other NYSE Amex Equities Rules. The definitions are discussed in greater detail in this filing where relevant.

3. Proposed Rule 502—NYSE Amex Equities (Hours of Business)

Pursuant to proposed Rule 502—NYSE Amex Equities, the Exchange proposes to trade Nasdaq Securities during regular trading hours in accordance with Rule 51—NYSE Amex Equities. Regular trading hours are usually from 9:30 a.m. to 4 p.m., or during such other hours as may be specified by Exchange rules or as otherwise determined by the Board of Directors of the Exchange. The Exchange also proposes to permit Nasdaq Securities to trade in the Exchange's "Off-Hours Trading Facility" under Rules 900—907—NYSE Amex Equities.[11] As described more fully below, however, due to modifications to the opening and closing for Nasdaq Securities, members and member organizations will not be permitted to make any bid, offer or transaction for Nasdaq Securities on Exchange systems, or route an order for a Nasdaq Security to another market center from Exchange systems, before 9:30 a.m. or after the

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and as used in the NYSE Amex Equities Rules. In accordance with this definition, Nasdaq Securities shall be admitted to dealings on the Exchange on an "issued", "when issued", or "when distributed" basis. *See* proposed Rule 501—NYSE Amex Equities.

[6] This sentence was revised per the e-mail from Jason Harmon, Consultant, NYSE Regulation, Inc., to Christopher Chow, Special Counsel, Commission ("April 9 e-mail"), dated April 9, 2010.

[7] *See* proposed Rule 500—NYSE Amex Equities. This is the same date that New York Stock Exchange LLC's ("NYSE") New Market Model pilot program expires. Because several elements of the Exchange's proposal to trade Nasdaq Securities rely on the NYSE's New Market Model ("NMM"), the Exchange proposes to extend the duration of this pilot program as needed to track the NYSE's NMM pilot program and would file for permanent approval at the same time or after the NYSE files for permanent approval of the NMM.

[8] The Exchange recently adopted Rule 107B—NYSE Amex Equities (Supplemental Liquidity Provider) to establish a new class of NYSE Amex Equities market participants. *See* Securities Exchange Act Release No. 61308 (January 7, 2010), 75 FR 2573 (January 15, 2010) (SR–NYSEAmex–2009–98).

[9] Although the Exchange may in the future seek to trade other Nasdaq Securities that are exchange traded funds or similar products as part of its pilot program, the Exchange's initial proposal is to limit the term "Exchange Traded Fund" to mean only the Invesco PowerShares QQQ™. *See* proposed Rule 501—NYSE Amex Equities. For the purposes of trading Nasdaq Securities all references to an "Exchange Traded Fund" or "ETF" in the NYSE Amex Equities Rules shall refer to the definition contained in proposed Rule 501—NYSE Amex Equities.

[10] As proposed, the NYSE Amex Equities Rule 500 Series is consecutively numbered from 500 to 525. However, some rules are expressly reserved and are not referenced in the filing herein.

[11] Currently, in accordance with NYSE Rule 1500, members and member organizations of NYSE (which includes substantially all NYSE Amex Equities members and member organizations) are also permitted to enter orders for Nasdaq-listed securities on a UTP basis into the NYSE MatchPoint facility ("NYSE MatchPoint"), which has an After-Hours matching session at 4:45 p.m. However, NYSE MatchPoint is not a system or facility of the Exchange, and thus the proposed NYSE Amex Equities Rule 500 Series, and Rule 502—NYSE Amex Equities in particular, would not apply to trading of Nasdaq-listed securities conducted on NYSE MatchPoint.

close of the Off-Hours Trading session (*e.g.* Crossing Session II).

4. Proposed Rule 504—NYSE Amex Equities (Nasdaq Security Assignment)

As described in this filing, the Exchange proposes to trade Nasdaq Securities within the existing DMM and SLP framework used to trade its listed securities. The Exchange will create a "Nasdaq Securities Liaison Committee", consisting of NYSE Euronext employees of the Operations and U.S. Markets Divisions (a representative of NYSE Regulation Inc. ("NYSER") would act as an ad hoc member of the Committee as needed), that will be responsible for reviewing and admitting Nasdaq Securities for trading on the Exchange. At the time Nasdaq Securities are admitted to dealings on the Exchange, the Nasdaq Securities Liaison Committee will assign each such security to a registered and qualified DMM Unit and registered and qualified SLPs in accordance with procedures substantially similar to the Exchange's current SLP procedures in Rule 107B—NYSE Amex Equities. *See* proposed Rule 501—NYSE Amex Equities. The Nasdaq Securities Liaison Committee may also, in its discretion, reassign one or more Nasdaq Securities to a different DMM Unit or to a different SLP or SLPs.

a. Assignment to DMM Units

Existing NYSE Amex Equities DMM Units will be automatically eligible for the assignment of Nasdaq Securities, so long as they qualify in accordance with Rules 98— and 103B(II)—NYSE Amex Equities, and proposed Rule 504(b)—NYSE Amex Equities.[12] For the purposes of trading Nasdaq Securities, the Exchange proposes to amend the quoting requirements under Rule 103B(II)—NYSE Amex Equities such that a DMM Unit shall be required to maintain a quote at the National Best Bid or Offer in each assigned Nasdaq Security an average of at least 10% of the time, or more, during the regular business hours of the Exchange for each calendar month. This quoting requirement is also part of a DMM Unit's affirmative obligations under proposed Rule 509—NYSE Amex Equities.

The Exchange's Nasdaq Securities Liaison Committee will assign Nasdaq Securities to DMM Units for trading on the Exchange. No more than one DMM Unit will be assigned to any Nasdaq Security and a member organization will not be permitted to be registered as both the DMM Unit and an SLP for the same Nasdaq Security.

b. Assignment of the Invesco PowerShares QQQ™

The Exchange intends to trade the Invesco PowerShares QQQ™ Exchange Traded Fund (the "QQQs") and has proposed a set of special requirements governing the assignment of the QQQs and its component securities.[13]

Under proposed Rule 504—NYSE Amex Equities, a DMM Unit may be registered in both the QQQs as well as a component security or securities of the QQQs provided that, at the time of assignment, (i) no single component in which the DMM Unit is registered exceeds 10% of the index or portfolio underlying the QQQs, and (ii) all components in which the DMM Unit is registered do not in the aggregate exceed 20% of the index or portfolio underlying the QQQs. Subsequently, if during any given month a single component security or group of securities in which the DMM Unit is registered exceeds these concentration measures on an average basis, the Nasdaq Liaison Committee will reassign either the QQQs or the component security or securities to another DMM Unit as needed to achieve compliance with the concentration measures.

The Exchange will calculate and monitor the components and percentage of the QQQs on a monthly basis in accordance with the proposed concentration measures and report these calculations to the Nasdaq Liaison Committee. In addition, under proposed Rule 504—NYSE Amex Equities the DMM Unit registered in the QQQs will have an independent obligation to calculate, monitor and report to the Exchange on a monthly basis the component security or securities in which it is registered, the average percentage of the underlying index or portfolio of each individual component during the month, and the total average aggregate percentage of the underlying index or portfolio of all components during the month. If these levels are exceeded the DMM Unit will be required to report this to the Exchange as soon as possible.

The Exchange recognizes that integrated market-making and side-by-side trading in related securities have sometimes raised concerns about manipulation or improper coordination of trading between the related securities. As explained more fully below, the Exchange believes, however, that the structures proposed for assigning and trading the QQQs and a subset of its component securities within a single DMM Unit will reduce or substantially eliminate those concerns, and are therefore consistent with the requirements of the Act and Commission policy.

The Commission has extensively addressed the issue of integrated market making and side-by-side trading in the context of trading index ETFs and related options. In that guidance, the Commission has repeatedly stated that one of the touchstones is whether an ETF is "broad-based" and therefore poses a low risk of being susceptible to manipulation.[14] In making this assessment, the Commission has weighed whether the underlying component securities are sufficiently liquid and well-capitalized such that they are not individually susceptible to manipulation, together with whether the composition of the ETF as a whole is such that it is not unduly concentrated in a single security or a small number of securities. When an ETF meets both criteria, and therefore can be considered "broad-based", the Commission has explicitly permitted integrated market making and side-by-side trading in both the ETF and related options, with no requirement for information barriers or physical or organizational separation. *See, e.g.,* CBOE Rule 54.7(d).

The Exchange believes that the logic inherent in permitting integrated market making in broad-based ETFs and related options should also apply to permit integrated market making in a broad-based ETF such as the QQQs and a limited number of its component securities. The Exchange notes at the outset that there do not appear to be rules on other exchanges expressly

[12] The Exchange proposes to amend Rule 98(b)(2) (definition of "DMM unit") and (b)(15) (definition of "Related products")—NYSE Amex Equities to accommodate the trading of Nasdaq Securities on the Exchange.

[13] *See* proposed Rule 501(b)—NYSE Amex Equities, which defines "Exchange Traded Fund" as "the Invesco PowerShares QQQ™."

[14] *See* Securities Exchange Act Release No. 46213 (July 16, 2002), 67 FR 48232 (July 23, 2002) (SR–Amex–2002–21) (order approving integrated market making of broad index-based ETFs and related options). *See also* Securities Exchange Act Release Nos. 56633 (October 9, 2007), 72 FR 58696 (October 16, 2007) (SR–ISE–2007–60) (order approving generic listing standards for ETFs based on both U.S. and international indices, noting they are "sufficiently broad-based in scope to minimize potential manipulation."); 55621 (April 12, 2007), 72 FR 19571 (April 18, 2007) (SR–NYSEArca–2006–86) (same); 54739 (November 9, 2006), 71 FR 66993 (November 17, 2006) (SR–Amex–2006–78) (same); 57365 (February 21, 2008), 73 FR 10839 (February 28, 2008) (SR–CBOE–2007–109) (order approving generic listing standards for ETFs based on international indices, noting they are "sufficiently broad-based in scope to minimize potential manipulation."); 56049 (July 11, 2007), 72 FR 39121 (July 17, 2007) (SR–Phlx–2007–20) (same); 55113 (January 17, 2007), 72 FR 3179 (January 24, 2007) (SR–NYSE–2006–101) (same); *and* 55269 (February 9, 2007), 72 FR 7490 (February 15, 2007) (SR–Nasdaq–2006–50) (same). The QQQs meet these criteria.

addressing the latter type of integrated market making, nor has the Exchange identified guidance from the Commission specifically addressing the subject. Nevertheless, the Exchange believes that the extant Commission guidance on integrated market-making and side-by-side trading in broad-based ETFs and related options is highly relevant and informative to the current proposal, and is consistent with the Exchange's proposal.

Among other things, the Exchange's current proposal is limited to a single broad-based ETF, the QQQs, which meets the composition and concentration measures previously approved by the Commission (*see* footnote 14 herein) to be classified as a broad-based ETF, with minimal, if any, potential to be manipulated.

Because the potential for manipulation of the QQQs is so minimal, the risk presented by limited integrated market making is also extremely low. In this regard, the Exchange notes that the QQQs is one of the most actively traded securities in the world. It is based on a group of highly liquid securities (the top 100 Nasdaq-listed securities, ex-financial stocks); with the exception of Apple, no component represents more than 10% of the index; the ETF is itself very liquid (with 3-month average volume in excess of 90 million shares per day); and it is actively traded in multiple markets around the world.

Given all of this, the Exchange believes that it would be inherently ineffective to attempt to either manipulate the price of a component or front-run pending nonpublic trading activity in a component in order to effect an advantageous trade in the QQQs. First, because of the inherent leverage of the QQQs compared to its components, such a manipulation of a component would require a disproportionately large amount of capital in order to be able to both impact the price of the QQQs and simultaneously override potential concurrent and counter-cyclical price movements in the other 99 components. The amount of capital required to successfully accomplish such a manipulation would seemingly be larger than the potential profit potential. Similarly, the potential for successful front-running would require that the impact of the pending component trading activity not be neutralized by price changes in the other components. For the same reasons, it would be difficult to effectively front-run information about a component security by trading in the QQQs. However, as noted above, in order to mitigate against the theoretical possibility of successful manipulation or front-running, the Exchange would only permit the QQQs DMM to also be the DMM in a limited number of component stocks. *See* proposed Rule 504—NYSE Amex Equities.

The existence of a manual market on the Trading Floor does not materially alter this fundamental risk calculus. First, there will be few, if any, circumstances in which a DMM in a Nasdaq Security will be in possession of material nonpublic order information (*i.e.,* a pending block transaction) that could be used improperly. These situations are typically limited to circumstances when the market is slow because of a pending manual trade and/or when a Floor broker communicates that he or she is seeking to execute a block sized order. In listed securities today, a substantial percentage of manual trades occur in connection with the opening and closing auction or when a liquidity replenishment point ("LRP") has been reached. However, there will not be an opening or closing auction in Nasdaq Securities and the LRPs will be substantially widened. Thus the number of manual trades is anticipated to be negligible. And, even when a manual transaction in a component security does occur intraday (*e.g.,* in response to an LRP or publication of a gap quote), it is highly unlikely that a DMM Unit could profitably use this information to effect an advantageous trade in the QQQs for the reasons described above.

Second, the Exchange will not be the listing market in Nasdaq Securities and is expected to have limited market share given the fragmentation of trading in Nasdaq-listed securities in the U.S. equities markets. Thus any trading that occurs on the Exchange will generally equalize to trading on other markets, with limited, if any, ability for the DMM to materially impact the price of a component. In view of the depth and liquidity of the Nasdaq-100 component securities, the Exchange does not believe that a block transaction in a component security of the QQQs would necessarily impact the price of the component security on a consolidated basis for a meaningful period of time. More importantly, the Exchange does not believe that a block transaction on the Exchange in a component security would predictably impact the price of the QQQs for enough time, if at all, to alter the risk-reward calculus and incentivize front-running the component block transaction by trading in the QQQs. Given the high-speed pace of electronic trading generally, the breadth of markets where the QQQs is traded, and the average daily trade volume, the Exchange believes it to be highly unlikely that an individual standing on the Trading Floor could enter a timely trade in response to knowledge of a pending block trade in one of the component securities. For the same reasons, it would also be inherently unprofitable for a DMM to attempt to manipulate a component in order to effect an advantageous trade in the QQQs.

In view of these concerns, however, even if unlikely, as described above the Exchange proposes to adopt concentration requirements for trading the QQQs to limit the level of nonpublic information regarding the component securities available to the assigned QQQs DMM Unit. Together with the market structure considerations outlined above which mitigate against possible manipulation and front-running, the Exchange believes that this additional restriction will provide a "belt-and-suspenders" level of protection.

The Exchange also believes that any potential concerns over "wash sales" or inadvertent internal proprietary crosses by the DMM Unit are sufficiently addressed. First, Exchange DMM algorithmic trading systems (commonly known as the "SAPI") prevent DMM Unit trading interest from executing against its own quotes or other trading interest on the Exchange (*i.e.* an "internal cross") and virtually all DMM Unit trading interest is entered via the SAPI. While a DMM Unit could, theoretically, enter a proprietary order in one of its assigned securities other than through the SAPI, which would not be subject to the systemic internal cross block, that possibility is remote since the DMM Unit would incur higher fees for such an order and less advantageous parity treatment in connection with any execution of such order. Even so, DMM Units are required to have policies and procedures in place reasonably designed to prevent violations of Exchange rules and the federal securities laws, including NYSE Amex Disciplinary Rule 476(a)(8), which prohibits "giving an order for the purchase or sale of securities the execution of which would involve no change of beneficial ownership or executing such an order with knowledge of its character", as well as violations of the "wash sale" prohibition of Section 9 of the Act. These policies and procedures, including those governing a firm's risk management trading policies

and systems, are subject to review and approval by the Exchange.[15]

In addition, because any firm assigned as the DMM Unit for the QQQs will have, as part of its broader risk management capability, a unique ability to view and assess its trading activity across any and all markets in which it trades the QQQs and any components in which it is registered on the Exchange,[16] in accordance with Rule 342—NYSE Amex Equities the Exchange will require the QQQs DMM to implement adequate policies and procedures to detect and deter the inappropriate access to information about pending block trades in a component security, potential front-running and/or manipulation based on such information, intentional wash sales, or any other violations of Section 9 of the Act. The DMM's policies and procedures would also be required to provide that the DMM firm will conduct surveillance to identify patterns of trading that are indicative of possible front-running of block trades, manipulation and/or intentional wash sales, and to take appropriate steps to investigate and report such trading to the Exchange. As with all DMM Units, the firm will be subject to periodic and, if warranted, special examinations by FINRA.

As a result, the Exchange believes that the requirements governing the assignment of Nasdaq Securities in proposed Rule 504—NYSE Amex Equities are sufficient to address any market concerns. The Exchange also agrees to review proposed Rule 504—NYSE Amex Equities and the provisions governing the allocation of the QQQs and its component securities in the event that the Exchange's share of the market for the Nasdaq Securities it trades exceeds 10% of the consolidated Tape C aggregate average daily trading volume for these securities.

c. Integration of NYSE Amex Listed Securities and Nasdaq Securities at Posts on the Trading Floor

The Exchange anticipates that some DMM Units currently registered on the NYSE will seek to register as DMM Units on the Exchange in order to trade Nasdaq Securities. Under Exchange Rules, all current NYSE members and member organizations are deemed members and member organizations of the Exchange and DMM Units are automatically granted an NYSE Amex Equities trading license. *See* Rules 2.10— and 2.20—NYSE Amex Equities. Those NYSE DMM Units that wish to trade Nasdaq Securities and that are not already registered as DMM Units on the Exchange will need to register as such with the Exchange to ensure proper tracking and systems configuration. Similarly, individual DMMs will need to register with the Exchange to confirm that they meet all applicable registration requirements and to ensure proper tracking and systems set-up, including ID Track requirements. In addition, NYSE DMM Units seeking to register as a DMM Unit on the Exchange will also need to advise FINRA in order to enable FINRA to assess whether such registration triggers different and/or additional financial and operational requirements, including but not limited to those pertaining to net capital.

As described more fully in the section proposing to amend Rule 103B—NYSE Amex Equities, *infra,* a DMM Unit that is registered to trade both NYSE and Exchange-listed securities, as well as Nasdaq Securities, could trade all these securities at the same post. However, such member organizations will be required to commit sufficient staff for the trading of NYSE-listed securities separate from that for the trading of Exchange-listed securities and/or Nasdaq Securities at the same post on the Trading Floor: individual DMMs and support staff will not be permitted to trade both NYSE-listed and NYSE Amex-listed securities and/or Nasdaq Securities at the same time. Intraday moves of individual DMMs and support staff between panels will be permitted, although DMMs and staffers will not be permitted to be simultaneously logged-into both an NYSE panel and an Exchange panel.

Finally, in conjunction with Rule 103B(IX), proposed Rule 504(d)—NYSE Amex Equities will require that Nasdaq Securities be allocated for trading only at panels exclusively designated for trading listed and/or Nasdaq Securities on the Exchange (*see infra*).

d. Assignment to SLPs

NYSE Amex Equities members and member organizations may apply to be SLPs in Nasdaq Securities and will be eligible for the assignment of Nasdaq Securities once they register and qualify as SLPs in accordance with Rule 107B—NYSE Amex Equities. As with NYSE registered DMMs and DMM Units, NYSE registered SLPs are automatically deemed member organizations of NYSE Amex Equities under Rule 2.10—NYSE Amex Equities. NYSE registered SLPs that wish to trade Nasdaq Securities as SLPs will need to register with and be approved by the Exchange as SLPs in accordance with all applicable NYSE Amex Equities Rules.

The Nasdaq Securities Liaison Committee will assign one or more SLPs to Nasdaq Securities for trading on the Exchange. A member organization cannot be both the DMM Unit and an SLP for the same Nasdaq Security. Because SLPs do not have a presence on the Trading Floor and do not have access to the information there, however, the Exchange does not propose the same limitations on the assignment of ETFs and component securities to SLPs as it does for DMM Units.

Finally, in the event an SLP withdraws from its status as an SLP, Nasdaq Securities will be reassigned to a different SLP(s) in accordance with Rule 107B—NYSE Amex Equities.

5. Proposed Rule 506—NYSE Amex Equities (Units of Trading; Bids and Offers; Dissemination of Quotations; Priority)

Nasdaq Securities will be traded almost exactly as the Exchange's listed securities. Proposed Rule 506—NYSE Amex Equities prescribes the basic unit of trading for Nasdaq Securities, and addresses some requirements for bids and offers, the dissemination of quotations, and priority and parity of executions of Nasdaq Securities.

The Exchange will accept and process bids and offers in Nasdaq Securities according to the same rules for its listed securities. In accordance with Rules 55— and 56—NYSE Amex Equities, the unit of trading in Nasdaq Securities is 100 shares, rights or warrants, or such lesser number as may be determined by the UTP Listing Market or the Exchange. Odd-lot bids or offers will be processed and executed by means of the Exchange's odd-lot order system pursuant to Rule 124—NYSE Amex Equities. The round-lot and odd-lot portions of partial round-lot orders will be processed and executed in accordance with Rule 124—NYSE Amex Equities.

Bids and offers in Nasdaq Securities admitted to dealings on the Exchange on an "issued" basis shall be made "regular way" in accordance with Rules 64—, 65— and 66—NYSE Amex Equities and, for Nasdaq Securities admitted on a "when-issued" or "when-distributed" basis, bids and offers shall only be made "when-issued" or "when-distributed" in accordance with Rule 63—NYSE Amex Equities.

[15] The member firm currently anticipated to be assigned as the DMM Unit in the QQQs has represented to the Exchange that the firm's risk management system will reasonably prevent the firm from effecting any internal proprietary crosses in its assigned securities.

[16] Such firm's risk management policies and procedures will have to meet the requirements of Rule 98—NYSE Amex Equities.

As enforced by Exchange systems, bids and offers in Nasdaq Securities shall comply with Rule 19—NYSE Amex Equities concerning locking or crossing protected quotations in Regulation NMS stocks and the Exchange shall disseminate quotes in accordance with Rule 60—NYSE Amex Equities. Also, the minimum price variations prescribed in Rule 62—NYSE Amex Equities shall apply to all bids and offers in Nasdaq Securities.

Orders for Nasdaq Securities shall be executed in price and time priority and parity in accordance with all applicable NYSE Amex Equities Rules, including Rule 72—NYSE Amex Equities.

The Exchange will display on the Trading Floor quotes and executions for Nasdaq Securities on both the Exchange as well as from other market centers in accordance with the UTP Plan ("Tape C"). Such display will include the appropriate identifier indicating the SRO or exchange reporting the execution to the Tape. Corporate action data for Nasdaq Securities will be incorporated by the Exchange on a daily basis after the close of regular trading and any adjustments to share price will be made at that time.

6. Proposed Rule 508—NYSE Amex Equities (Openings and Closings)

Pursuant to proposed Rule 508—NYSE Amex Equities, the Exchange proposes to conduct openings and closings for Nasdaq Securities differently than for listed securities. As described more fully below, the Exchange will not conduct an opening or closing auction in Nasdaq Securities and will instead open trading on a quote at 9:30 a.m. and close on the last sale price on the Exchange at 4 p.m.

a. Openings

Under proposed Rule 508(a), trading in Nasdaq Securities will not open based on an opening auction but will instead open at 9:30 a.m. or as soon thereafter as possible, or at such other time as may be specified by the Exchange, based on a quote published by the DMM Unit assigned to each particular security. Orders for Nasdaq Securities shall not be accepted by the Exchange and will be systemically blocked before trading opens on any business day.

The DMM Unit will be responsible for opening trading in its assigned Nasdaq Securities by publishing an opening quote at 9:30 a.m. or as soon thereafter as possible. Because Nasdaq Securities will open on a quote, DMM Units will not be permitted or required to provide pre-opening or opening indications as prescribed by Rules 15— and 123D—NYSE Amex Equities. In addition, because the Exchange will not conduct an opening auction for Nasdaq Securities, DMM Units will not be permitted or required to hold or represent orders for Nasdaq Securities pursuant to Rule 115A.20—NYSE Amex Equities.

b. Closings

Under Rule 508(b), trading in Nasdaq Securities will not close based on a closing auction but will instead close at the end of the regular trading session at 4 p.m., or at such other time as may be specified by the Exchange. Except for "aggregate-price orders",[17] or "closing-price orders" entered to offset an error, entered in the "Off-Hours Trading Facility" in accordance with proposed Rule 511—NYSE Amex Equities, orders for Nasdaq Securities will not be accepted by the Exchange after the regular trading session on any business day.[18]

The "Closing Price" will be set at the price of the last sale in a Nasdaq Security on the Exchange at or prior to the close of regular trading at 4 p.m. (*see* Rules 502— and 508—NYSE Amex Equities).[19] Orders for Nasdaq Securities that are unexecuted at the close of trading at 4 p.m. shall be cancelled.

If, at or just prior to the close of trading at 4 p.m., the market for a particular Nasdaq Security is manual or "slow" (for example, because a gap quote has been published or a Liquidity Replenishment Point has been reached), there will be a single trade at or immediately after the close that will set the Closing Price. In such circumstances, the DMM will pair off liquidity to the extent available and then execute the final trade. All residual marketable interest for that security received prior to the close of trading shall first be executed at the Closing Price and then all unexecuted interest for the security shall be cancelled.

When the market for a Nasdaq Security is slow at the close of trading, the DMM Unit must execute the final trade in the security in a manner consistent with a fair and orderly market, with reference to the trading characteristics of the stock at issue, including its price, average daily trading volume ("ADTV"), average volatility, the prior sale of the security on the Exchange and the closing price on the UTP Listing Market. To ensure this, Floor Governor approval is required to close a Nasdaq Security that is "slow."

In the event of an extreme order imbalance at or near the close of the regular trading session that could result in Closing Price dislocation, the procedures of Rule 123C(9)—NYSE Amex Equities, which permit the Exchange to temporarily suspend the hours of operation for the solicitation and entry of orders into Exchange systems, shall apply. However, because the Exchange will not conduct a closing auction in Nasdaq Securities, no other procedures of Rule 123C—NYSE Amex Equities shall apply to trading in Nasdaq Securities.

The proposed modifications to the opening and closing of the trading of Nasdaq Securities require corresponding modifications to the "GTC" and "Stop" order types. Specifically, GTC Orders and unelected Stop Orders for Nasdaq Securities that are not fully executed at the close of the regular trading session shall be treated as Day Orders and shall be cancelled; they will not remain on the Exchange's systems overnight. In addition, because the Exchange will not conduct either an opening or closing auction in Nasdaq Securities, the Exchange will not accept MOC/LOC, OPG, CO or GTX Orders for Nasdaq Securities. All other order types noted in Rule 13—NYSE Amex Equities will be permitted for the trading of Nasdaq Securities.[20]

7. Proposed NYSE Amex Equities Rule 509 (Dealings of DMM Units and SLPs)

As noted above, the Exchange proposes to trade Nasdaq Securities using the same DMM/SLP framework as currently used for its listed securities.

a. DMM Units

DMM Units registered to trade Nasdaq Securities on the Exchange will be required to fulfill their responsibilities and duties for those securities in accordance with all applicable NYSE Amex Equities Rules and requirements ("DMM rules"),[21] subject to two modifications.

Under Rule 104—NYSE Amex Equities, for those Exchange-listed securities in which they are registered, DMM Units are required to use their capital to meet the obligation of maintaining a fair and orderly market to the extent reasonably practicable. This requirement, in turn, may be broken down into certain components, which

[17] The Exchange is proposing to amend the definition of "aggregate-price order" under Rule 900—NYSE Amex Equities in order to accommodate trading Nasdaq Securities in the Off-Hours Trading Facility.

[18] These terms are defined under Rule 900—NYSE Amex Equities.

[19] *See also* proposed Rule 501—NYSE Amex Equities.

[20] *See* proposed Rule 501—NYSE Amex Equities.

[21] The term "DMM rules" is defined under Rule 98—NYSE Amex Equities.

include quoting at the National Best Bid or National Best Offer for a certain percentage of time, supplying liquidity as needed, managing and/or facilitating manual or other transactions at specified times, minimizing and stabilizing disparity in supply and demand as needed, and maintaining price continuity and depth within specified guidelines. None of these individual requirements is dispositive and they must all be viewed together when evaluating the broader obligation to maintain a fair and orderly market.[22]

In return for those obligations and restrictions, DMM Units are entitled to trade on parity with Floor brokers and off-Floor orders in their registered securities, are the sole market maker on the Exchange in those securities, and receive financial incentives for providing liquidity and executing odd-lot orders. DMM Units also have the ability to set a Capital Commitment Schedule ("CCS"), which allows them to indicate to Exchange systems where they are willing to add additional liquidity to the market; if these pre-determined parameters are met, the system automatically includes the additional CCS interest.[23]

For Nasdaq Securities, DMM Units will, insofar as reasonably practicable, continue to be responsible for engaging in a course of dealings for their own account and assisting in the maintenance of a fair and orderly market for those securities in which they are registered in accordance with Rule 104—NYSE Amex Equities. There are two modifications, however.

First, in lieu of the tiered quoting requirement (5% and 10%) currently in place for listed securities under Rule 104(a)(1)(A)—NYSE Amex Equities, proposed Rule 509(a)(1) requires a DMM Unit to maintain a quote at the National Best Bid or Offer ("inside") in each assigned Nasdaq Security an average of at least 10% of the time, or more, during the regular business hours of the Exchange for each calendar month. As for listed securities, time at the inside will be calculated as the average of the percentage of time the DMM Unit has a bid or offer at the inside, and credit will be given for executions for the liquidity provided by the DMM Unit. Reserve or other hidden orders entered by the DMM Unit will not be included in the inside quote calculations. Because this quoting requirement will be applied on a stock-by-stock basis, rather than aggregated across all securities that the DMM Unit trades, the Exchange believes it is a more stringent standard than is currently in place for listed securities.

Second, pursuant to Rules 104(f)(ii)—and (iii)—NYSE Amex Equities, DMM Units will continue to be responsible for maintaining price continuity with reasonable depth for their registered Nasdaq Securities in accordance with Depth Guidelines published by the Exchange. However, in order to give the Exchange time to phase-in appropriate Depth Guidelines, these provisions will not be operative until 18 weeks after the approval of the proposed rule changes by the Commission.[24]

As is the case with listed securities, DMM Units will also be responsible for facilitating openings, reopenings and closings for each of the Nasdaq Securities in which they are registered in accordance with applicable NYSE Amex Equities Rules, including the procedures of proposed Rules 508– and 515—NYSE Amex Equities. DMM Units will also be responsible for facilitating trading when the market is "slow" (such as during a gap quote or an LRP) [25] and helping to close Nasdaq Securities that are subject to an imbalance. Other obligations would continue to apply, including providing contra side liquidity as needed for the execution of odd-lot orders for Nasdaq Securities received on the Exchange, meeting stabilization and re-entry requirements, and complying with the net capital requirements under Rules 103.20—, 4110— and 4120—NYSE Amex Equities, as well as the Act.

Because DMMs would retain obligations that other market participants, both on the Exchange and in other markets, do not have, DMM Units would retain the benefits of parity and liquidity incentives, as well as the ability to use CCS, when trading Nasdaq Securities.[26] In addition, DMMs would continue to be the sole market maker on the Exchange in their registered Nasdaq Securities.

The Exchange believes the enhanced quoting requirement and phased-in Depth Guidelines are appropriate in connection with trading Nasdaq Securities on the Exchange, particularly because the market dynamics for trading Nasdaq Securities will be different from those for the Exchange's listed securities. Although the Exchange will not be the primary market for Nasdaq Securities and its market share is expected to be small, at least initially, the Exchange believes that its DMM/SLP market model will, for some market participants, provide an attractive and competitive alternative for the trading of Nasdaq Securities that does not currently exist.

In addition, other provisions of the NYSE Amex Equities Rules related to DMM responsibilities and obligations would be modified, including the following:

- DMMs will not be required to obtain Floor Official approval prior to engaging as a dealer in transactions for Nasdaq Securities that fall under Rule 79A.20—NYSE Amex Equities.
- Notwithstanding the prescriptions of Rule 36.30—NYSE Amex Equities governing communications to and from the DMM Unit post on the Trading Floor, an individual DMM registered in an ETF may use a telephone connection or order entry terminal at the DMM Unit's post to enter a proprietary order in the ETF in another market center, in a component security of such ETF, or in an options or futures contract related to such ETF, and may use the post telephone to obtain public market information with respect to such ETF, options, futures, or component securities. If the order in the component security of the ETF is to be executed on the Exchange, the order must be entered and executed in compliance with Rule 112—NYSE Amex Equities and SEA Rule 11a2–2(T), and must be entered only for the purpose of creating a bona fide hedge for a position in the ETF. The Exchange is proposing to add this provision in order to permit DMM Units registered in an ETF to execute more efficiently hedging transactions for the security.[27]

[22] *See* Rules 72– and 104—NYSE Amex Equities. For a more detailed discussion of DMM obligations, *see* Securities Exchange Act Release No. 58845 (October 24, 2008), 73 FR 64379 (October 29, 2008) (SR–NYSE–2008–46).

[23] *See* Rules 72–, 104(d)– and 1000—NYSE Amex Equities concerning parity and CCS. For information on the rebate structure, *see* the Exchange's price list, available on the Exchange Web site at *http://www.nyse.com*.

[24] A phased-in approach is necessary so that appropriate Depth Guidelines may be calculated based on actual trading data of Nasdaq Securities on the Exchange. Accordingly, following implementation and roll-out of the pilot program, the Exchange proposes to collect 60 trading days of trade data and would then implement Depth Guidelines for trading Nasdaq Securities on NYSE Amex within 30 calendar days of the collection of the trade data. The eighteen week phase-in period contemplates a two-week period to roll-out the pilot program.

[25] For clarification, a DMM Unit facilitates trading in slow markets by either conducting an auction or trading out of the slow market in order to resume a "fast" (*i.e.* quote protected) market. It does not mean, however, that a DMM Unit must participate on the contra-side of the market when it is slow.

[26] The Exchange will submit a separate fee filing detailing the rebate structure for trading Nasdaq Securities at a later date.

[27] This provision is modeled on a provision in NYSE Rule 36.30, approved by the Commission. *See* Securities Exchange Act Release No. 44616 (July 30, 2001), 66 FR 40761 (August 3, 2001) (SR–NYSE–2001–08) (order approving amendments to NYSE Rule 36.30).

b. SLPs

SLPs registered in one or more Nasdaq Securities must fulfill their responsibilities and duties for those securities in accordance with all applicable NYSE Amex Equities Rules and requirements, including, but not limited to, the requirements of Rule 107B—NYSE Amex Equities, and the SLP quoting requirements for Nasdaq Securities shall be the same as for securities listed on the Exchange.

8. Proposed NYSE Amex Equities Rule 510 (Derivative Securities Products)

The Exchange also proposes some specific additional provisions that will apply to the trading of Exchange Traded Funds that are "new derivative securities products," as defined in Rule 19b–4(e) under the Act and traded pursuant to Rule 19b–4(e) thereunder.[28]

For each such ETF, the Exchange will file a Form 19b–4(e) with the Commission. In addition, the Exchange will distribute an information circular prior to the commencement of trading in each such product that generally includes the same information as contained in the information circular provided by the UTP Listing Market for the product, including: (a) The special risks of trading the new product; (b) the Exchange Rules that will apply to the new product, including Rule 405—NYSE Amex Equities; (c) information about the dissemination of the value of the underlying assets or indexes; and (d) the risks of trading outside of the regular trading session for the product due to the lack of calculation or dissemination of the value of the underlying assets or index, the intra-day indicative value or a similar value.

Members and member organizations that trade these ETFs will be subject to the prospectus delivery requirements of the Securities Act of 1933, unless the product is the subject of an order by the Commission exempting the product from certain prospectus delivery requirements under Section 24(d) of the Investment Company Act of 1940 or the product is not otherwise subject to prospectus delivery requirements under the Securities Act of 1933. As a result, members and member organizations will be required to provide all purchasers of such an ETF with a written description of the terms and characteristics of the product at the time confirmation of the first transaction in the product is delivered to the purchaser. In addition, members and member organizations will be required to include a written description with any sales material relating to the product that they provide to customers or the public. Any other written materials provided by a member or member organization to customers or the public making specific reference to the ETF as an investment vehicle must include a statement that such materials are available.

Members or member organizations carrying omnibus accounts for non-members will be required to inform non-members that execution of an order to purchase an ETF for the omnibus account will be deemed to constitute agreement by the non-member to make such written description available to its customers on the same terms as are directly applicable to members and member organizations under this Rule. Upon request of a customer, a member or member organization shall also provide a prospectus for the particular product.

In order to accommodate the trading of ETFs that qualify under this Rule, the Exchange is also proposing additional requirements for trading halts. If a temporary interruption occurs in the calculation or wide dissemination of the intraday indicative value, the value of the underlying index, portfolio or instrument, or similar value of a product and the UTP Listing Market halts trading in the product, the Exchange, upon notification by the UTP Listing Market of such halt due to such temporary interruption, shall also immediately halt trading in that product.

If the interruption in the calculation or wide dissemination of the intraday indicative value, the value of the underlying index, portfolio or instrument, or similar value continues as of the commencement of trading on the Exchange on the next business day, the Exchange shall not commence trading of the product on that day. If the interruption in the calculation or wide dissemination of the intraday indicative value, the value of the underlying index, portfolio or instrument, or similar value continues, the Exchange may resume trading in the product only if calculation and wide dissemination of the intraday indicative value, the value of the underlying index, portfolio or instrument, or similar value resumes or trading in the product resumes on the UTP Listing Market.

For an ETF where a net asset value or disclosed portfolio is disseminated, the Exchange will immediately halt trading in such product upon notification by the UTP Listing Market that the net asset value or disclosed portfolio is not being disseminated to all market participants at the same time. The Exchange may resume trading in the product only when dissemination of the net asset value or disclosed portfolio to all market participants at the same time resumes or trading in the product resumes on the UTP Listing Market.

For an ETF that is listed on Nasdaq, such as the QQQs, Nasdaq rules require and/or permit it to halt trading in such securities when net asset value or other information is not being properly disseminated as required (*see* Nasdaq Rule 4120(a)(9)–(10)).[29] Pursuant to the UTP Plan, Nasdaq is required to use the national market system communication media ("Hoot-n-Holler") to notify other participants of such a halt and upon such notification the Exchange would halt trading in the QQQs in accordance with the proposed rules.

Finally, due to the nature of ETFs such as the QQQs, the Exchange proposes to restrict the allocation of that security and its components. *See* proposed Rule 504—NYSE Amex Equities. In addition, the Exchange will enter into a comprehensive surveillance sharing agreement with markets trading components of the index or portfolio on which the product is based to the same extent as the UTP Listing Market's rules require the UTP Listing Market to enter into a comprehensive surveillance sharing agreement with such markets.

9. Proposed NYSE Amex Equities Rule 511 (Off-Hours Trading)

Nasdaq Securities will be accepted by the Exchange's Off-Hours Trading Facility as part of an aggregate-price ("basket") order, or as a closing-price order entered to offset a transaction made in error, as those terms are defined under Rule 900—NYSE Amex Equities.[30]

10. Proposed NYSE Amex Equities Rule 512 (Liquidity Replenishment Points)

Given the different trading characteristics of Nasdaq Securities, the Exchange proposes to amend the values used to calculate Liquidity Replenishments Points (LRPs) for these securities in accordance with Rule 1000—NYSE Amex Equities.

[28] These provisions are based on similar rules adopted by other exchanges and/or approved by the Commission for the generic trading of derivative securities products based on unlisted trading privileges. *See, e.g.,* Securities Exchange Act Release No. 57448 (March 6, 2008), 73 FR 13597 (March 13, 2008) (SR–NSX–2008–05) (order approving NSX Rule 15.9) *and* Securities Exchange Act Release No. 59663 (March 31, 2009), 74 FR 15552 (April 6, 2009) (SR–Nasdaq–2009–018) (notice of filing and immediate effectiveness for Nasdaq Rule 5740).

[29] *See* April 9 e-mail.

[30] The Exchange is proposing to amend the definition of "aggregate-price order" under Rule 900—NYSE Amex Equities in order to accommodate trading Nasdaq Securities in the Off-Hours Trading Facility. *See* Exhibit 5.

The Exchange expects that Nasdaq Securities will be much more thinly traded on the Exchange, with lower volume and less liquidity than its listed securities, and that prices for Nasdaq Securities will be more volatile. As a result, in order to avoid triggering too many "slow" trading situations, the Exchange proposes wider LRP parameters for trading Nasdaq Securities than for its listed securities. Specifically, the Exchange proposes that, for each Nasdaq Security (except for ETFs), the value used to calculate the LRP ranges shall be ten percent (10%) of the Closing Price of the relevant security from the prior regular trading session on the Exchange, rounded to the nearest penny. These values will be recalculated by the Exchange on a daily basis. For the first day of trading of each Nasdaq Security, the LRP will be calculated using the Nasdaq closing price from the prior trading session.

Upon the phase-in period, the Exchange intends to evaluate these parameters to determine if they need to be adjusted in light of trading activity for Nasdaq Securities on the Exchange.

11. Proposed NYSE Amex Equities Rules 513 (Trading Ahead of Customer Limit Orders) and 514 (Trading Ahead of Customer Market Orders)

As described more fully below, proposed Rules 513— and 514—NYSE Amex Equities prescribe limitations on proprietary trading by members and member organizations holding unexecuted customer orders in Nasdaq Securities. In summary, a member firm handling an unexecuted customer order in a Nasdaq Security will not be permitted to execute a proprietary trade for that security at a price that would satisfy the customer's order without executing the customer's order at that price.

In order to harmonize the obligations for members and member organizations trading Nasdaq Securities on the Exchange with their existing obligations for trading those securities off-Exchange, proposed Rules 513— and 514—NYSE Amex Equities are substantially similar to FINRA's "Manning Rule" (NASD Interpretive Material 2110–2 and NASD Rule 2111). Subject to some technical amendments to apply the Rules to the Exchange, proposed Rule 513—NYSE Amex Equities is based on NASD IM–2110–2 and proposed Rule 514—NYSE Amex Equities is based on NASD Rule 2111. Correspondingly, proposed Rules 513— and 514—NYSE Amex Equities exempt Exchange members and member organizations from Rule 92—NYSE Amex Equities for the purposes of trading Nasdaq Securities.

There are several reasons for adopting a Manning-like set of rules rather than applying Rule 92—NYSE Amex Equities. To begin with, all Exchange member organizations that have public customers are also FINRA members and are therefore subject to FINRA's Manning Rule when trading off-Exchange. In addition, because the Manning Rule and Rule 92—NYSE Amex Equities differ in certain key aspects, the Exchange believes that requiring member organizations to comply with two sets of potentially conflicting standards when trading Nasdaq Securities would be confusing and would require programming changes by member organizations.[31]

Rule 92—NYSE Amex Equities prohibits, subject to some exceptions, members and member organizations from entering proprietary orders if the person responsible for the entry of that order has knowledge of an unexecuted customer order on the same side of the market that could be executed at the same price as the proprietary order.[32] Rule 92 does, however, permit a member or member organization to enter a proprietary order for certain specified purposes while representing a customer order that can be executed at the same price where the customer order is not held and is for either an institutional account or is greater than 10,000 shares and $100,000 in value ("Institutional/Large-size Order"), provided that the member or member organization has provided written disclosures and obtained documented affirmative consent from the customer. Rule 92 also permits an exception where a member or member organization enters a proprietary order to facilitate a riskless principal transaction. In addition, the prescriptions of Rule 92 do not apply to transactions made (i) by odd-lot dealers, (ii) on delivery terms different from those for the unexecuted customer order, (iii) by members or member organizations acting as market makers on other markets, (iv) to correct bona fide errors, and (v) as intermarket sweep orders made in compliance with Regulation NMS.[33]

By comparison, the Manning Rule operates to prohibit a member firm from executing, rather than entering, a proprietary trade at a price equal to or better than an unexecuted customer order unless the firm immediately executes the customer order at the same price (or better) it executed its own proprietary order.[34] Like Rule 92—NYSE Amex Equities, the Manning Rule has an exception for Institutional/Large-size Orders, subject to disclosure to the customer. However, unlike Rule 92—NYSE Amex Equities, the Manning Rule does not require affirmative consent from the customer. In addition, the Manning Rule does not limit the specific types of transactions to which this exception applies. The Manning Rule has other exceptions that mirror those of Rule 92—NYSE Amex Equities, including for transactions made by a member as a riskless principal or involving intermarket sweep orders. The Manning Rule does not, however, permit exceptions for transactions on delivery terms different from those for the unexecuted customer order, by members or member organizations acting as market makers on other markets, or to correct bona fide errors.[35]

As is evident, Rule 92—NYSE Amex Equities differs from the Manning Rule, most notably in its focus on order entry rather than execution. Moreover, Rule 92—NYSE Amex Equities provides exceptions for certain types of transactions that the Manning Rule does not. Thus, any dual NYSE Amex Equities and FINRA member attempting to comply with both Rule 92—NYSE Amex Equities and the Manning Rule while trading Nasdaq Securities on the Exchange would be subject to differing standards for the same security solely because of where an order has executed.[36]

[31] Although there may be Exchange-only members that trade Nasdaq Securities, such members are not subject to the Manning Rule because they do not have public customers. Moreover, all Exchange members that are registered as Floor brokers are also required to be FINRA members and, unless proposed Rules 513— and 514—NYSE Amex Equities are approved, would be required to comply with both Rule 92—NYSE Amex Equities and the Manning Rule.

[32] Technically, Rule 92—NYSE Amex Equities refers to transactions involving "Exchange-listed securit[ies]", which would not encompass Nasdaq Securities traded on the Exchange. However, the Exchange recognizes that, whether it applies Rule 92 or the Manning Rule, some form of limitation will be prescribed on proprietary trading of Nasdaq Securities by members and member organizations due to customer orders.

[33] *See generally* Rule 92—NYSE Amex Equities.

[34] FINRA has proposed to combine NASD Interpretive Material 2110–2 and NASD Rule 2111 into a single FINRA Rule 5320. *See* Securities Exchange Act Release No. 61168 (December 15, 2009), 74 FR 68084 (October 22, 2009) (SR–FINRA–2009–090). *See also* FINRA Regulatory Notice 09–15 (March 12, 2009).

[35] *See* NASD Interpretive Material 2110–2 and NASD Rule 2111.

[36] There are other differences between Rule 92—NYSE Amex Equities and the Manning Rule, including each Rule's definition of "institutional account", the reporting requirements for executing riskless principal transactions, and minimum price improvement standards. The Exchange notes that it, NYSE and FINRA are in the process of harmonizing their respective customer order protection rules. For

Continued

Moreover, the Exchange understands that firms generally code their order entry, routing and execution systems to comply with Rule 92—NYSE Amex Equities when trading on the Exchange and the Manning Rule when trading on NASDAQ and other markets. It would be impractical and unnecessarily burdensome to require member organizations to add Rule 92—NYSE Amex Equities parameters to their systems to account for both the Manning Rule and Rule 92—NYSE Amex Equities when trading Nasdaq Securities on the Exchange.

Requiring firms to comply with proposed Rules 513— and 514—NYSE Amex Equities rather than Rule 92—NYSE Amex Equities when trading Nasdaq Securities comports with the broader goals of regulating the market for these securities. The majority of trading in Nasdaq Securities takes place on other markets in accordance with the requirements of the Manning Rule, and FINRA and other SROs conduct surveillance based on those parameters. Requiring member firms to comply with proposed Rules 513— and 514—NYSE Amex Equities rather than Rule 92—NYSE Amex Equities ensures that, when Nasdaq Securities are traded on the Exchange, FINRA and/or other SROs can properly surveil these trades in the context of the overall market for those securities.

Although firms will be required to comply with proposed Rules 513— and 514—NYSE Amex Equities rather than Rule 92—NYSE Amex Equities, there will not be any regulatory gaps. Currently, FINRA and the Exchange have an agreement pursuant to Section 17(d) of the Act and Rule 17d–2 thereunder (the "17d–2 Agreement") to allocate regulatory responsibility for oversight of certain Exchange Rules. The Exchange has proposed to FINRA to extend the regulatory oversight provided under the 17d–2 Agreement to include customer order protection of Nasdaq Securities and compliance with proposed Rules 513— and 514—NYSE Amex Equities, and, based on discussions with FINRA representatives, it is anticipated that FINRA will approve.

Notwithstanding the proposed exemption from Rule 92—NYSE Amex Equities, the Exchange will still require members and member organizations to comply with all other applicable NYSE Amex Equities Rules, any and all applicable rules or regulations of the UTP Listing Market or FINRA and the federal securities laws and the rules thereunder, related to proprietary trading while holding unexecuted customer orders in the same security.[37]

12. Proposed NYSE Amex Equities Rule 515 (Trading Halts)

Generally, as prescribed in proposed Rule 515—NYSE Amex Equities, the Exchange will follow all applicable NYSE Amex Equities Rules governing halts or suspensions, for both regulatory and/or non-regulatory purposes, of the trading of Nasdaq Securities on the Exchange, including Rules 51—, 80B—, 123D— and 510—NYSE Amex Equities.

In addition, the Exchange will halt or suspend trading in a Nasdaq Security when trading in that security has been halted or suspended by the UTP Listing Market for regulatory reasons in accordance with its rules and/or the UTP Plan.[38] The Exchange will also halt or suspend trading in a Nasdaq Security when the authority under which the security trades on the Exchange or the UTP Listing Market has been revoked. This can occur when the Nasdaq Security at issue is no longer designated as an "eligible security" pursuant to the UTP Plan or is no longer listed with the UTP Listing Market. Also, if the Exchange has removed a Nasdaq Security from dealings trading will be halted or suspended.[39]

In the event that trading of a Nasdaq Security or Nasdaq Securities is halted or suspended pursuant to proposed Rule 515—NYSE Amex Equities, trading of the affected security or securities on the Exchange will resume in accordance with the procedures of applicable NYSE Amex Equities Rules, including Rule 508—NYSE Amex Equities, the rules of the UTP Listing Market and/or the UTP Plan. Any orders for a Nasdaq Security that are unexecuted at the time trading is halted on the Exchange shall be cancelled and the Exchange shall not accept any new orders for the affected security for the duration of the halt.

13. Proposed Rules 516— and 518—NYSE Amex Equities (Reporting and Recordkeeping; Clearance and Settlement)

As described more fully below, under proposed Rule 516—NYSE Amex Equities: (1) Members and member organizations trading Nasdaq Securities on the Exchange are subject to Rules 123— and 132B—NYSE Amex Equities; (2) if a member or member organization is also a FINRA member subject to FINRA's Rule 7400 Series, such a firm is exempt from Rules 123— and 132B—NYSE Amex Equities; and (3) regardless of whether or not a FINRA member, a Floor broker that receives an order in a Nasdaq Security from another member via Exchange systems will be subject to Rules 123— and 132B—NYSE Amex Equities and exempt from FINRA's Rule 7400 Series.

Rules 123— and 132B—NYSE Amex Equities, *inter alia,* make up the Exchange's transaction audit trail system.[40] Specifically, Rule 132B—NYSE Amex Equities prescribes order tracking requirements for transactions conducted on the Exchange. In relevant part, members and member organizations are required to record and maintain certain details of an order in an electronic order tracking system ("OTS"). In addition, Rules 123(e)— and (f)—NYSE Amex Equities require members and member organizations that act as Floor brokers to record certain details of orders received on the Floor and executed on the Exchange in the Exchange's Front-End System Capture ("FESC"). Because the Exchange's members and member organizations must already comply with these requirements for the purposes of trading listed securities, trading Nasdaq Securities on the Exchange does not present any difficulties under these particular Rules.

However, the Exchange's OTS and FESC requirements are not the only audit trail requirements for trading Nasdaq Securities on the Exchange. Currently, most of the Exchange's members and member organizations are also FINRA members and FINRA requires all trades in Nasdaq-listed securities by its members, regardless of the market, to be reported to its Order Audit Trail System ("OATS"), FINRA Rule Series 7400. Although FINRA's

a full discussion comparing the two Rules and the proposed harmonization, *see* NYSE and NYSE Amex Equities Information Memo 09–13 (March 12, 2009) *and* FINRA Regulatory Notice 09–15 (March 12, 2009).

[37] All Exchange members or member organizations that send customer orders to the Exchange and have a public business are currently, or will be required to also be, FINRA members (*see* Rule 2(b)—NYSE Amex Equities), and thus would need to comply with the Manning Rule when trading Nasdaq Securities off-Exchange.

[38] Under proposed Rule 501—NYSE Amex Equities, the Exchange defines the term "UTP Listing Market" to have the same meaning as the term "Listing Market", as defined under the "UTP Plan" (also defined therein).

[39] The provisions of Rule 123D(4)—NYSE Amex Equities, which prescribe a special trading halt of "Structured Products" that were listed on the Exchange at the time the trading of equities securities migrated from the Exchange's legacy systems and facilities at 86 Trinity Place to 11 Wall Street, shall not apply to the trading of Nasdaq Securities.

[40] In addition, Rule 132A—NYSE Amex Equities requires members and member organizations to synchronize their business clocks for recording and Rule 132C—NYSE Amex Equities requires members and member organizations to transmit audit trail records to the Exchange upon request.

OATS contains substantially the same order information as the Exchange's OTS and FESC, FINRA's OATS data is in a different format from the data recorded by OTS and FESC and the systems are not directly compatible. As a result, for those dual NYSE Amex/FINRA members and member organizations that intend to enter and/or execute orders in Nasdaq Securities on both the Exchange and other markets, compliance with both the Exchange's and FINRA's audit trail requirements for the purposes of trading Nasdaq Securities on the Exchange is not readily feasible.

Due to this conflict, proposed Rule 516—NYSE Amex Equities includes an exemption from the requirements of Rules 123— and 132B—NYSE Amex Equities for any members or member organizations that are also FINRA members and subject to the requirements of FINRA's OATS (FINRA Rule 7400). In addition, because NYSE Amex has not previously traded Nasdaq-listed securities on the Exchange, some members and member organizations, particularly Floor brokers that have previously only conducted transactions in Exchange-listed securities, do not have OATS-compliant systems and procedures. With the introduction of trading Nasdaq Securities on NYSE Amex, certain members and member organizations (and/or the Exchange) could incur significant expense and/or delay if forced to convert to OATS-compliant systems.

To address this issue, the Exchange has sought, and expects to receive formal confirmation of, interpretive guidance from FINRA that its Rule 7440(c)(6) exempts from FINRA's OATS requirements those Floor brokers who, regardless of their FINRA membership, receive an order in a Nasdaq Security that is first routed to the Exchange through Exchange systems (*i.e.* the Common Customer Gateway, or "CCG").[41] Most orders received by a Floor broker are received through CCG, where the orders are automatically captured in the systems that feed the Exchange's audit trail and then processed in accordance with their instructions. However, in the case of orders in Nasdaq Securities that are received by a Floor broker by means other than an Exchange system (*e.g.,* orders received over the telephone), the Floor broker would need to comply with FINRA's OATS requirements. In addition, any Floor broker member firm approved to route orders away from the Exchange pursuant to Rule 70.40—NYSE Amex Equities, and orders in Nasdaq Securities handled by such firms, would be subject to FINRA's OATS requirements.

Under proposed Rule 516—NYSE Amex Equities the Exchange with [sic] have access to a complete audit trail and there will be no gap in regulatory oversight. For dual NYSE Amex/FINRA members, FINRA's OATS rules will apply to an order in a Nasdaq Security up to when it is routed to the Exchange. At that point, if the order is transmitted to a Floor broker via an Exchange system, the Exchange's OTS and FESC requirements will capture its subsequent handling and execution on the Exchange. And, all Exchange-only, non-FINRA members or member organizations will be subject to the Exchange's OTS and FESC requirements throughout the handling of an order for a Nasdaq Security. To ensure proper oversight of trading Nasdaq Securities, the Exchange and FINRA can provide each other with copies of relevant audit trail records and/or data pursuant to the Intermarket Surveillance Group ("ISG"). Similarly, NYSE Amex will disseminate reports of executions of Nasdaq Securities on the Exchange in accordance with applicable NYSE Amex Equities Rules and the UTP Plan.

Finally, under proposed Rule 518—NYSE Amex Equities, members and member organizations that conduct transactions involving Nasdaq Securities on the Exchange will be required to comply with all applicable NYSE Amex Equities Rules related to clearance and settlement of such transactions.

Including Rules 123— and 132B—NYSE Amex Equities, Rules 342— and 351—NYSE Amex Equities, which require members and member organizations to provide any trading information requested by the Exchange, also need to be amended. In particular, the Exchange proposes to add language to each of these rules specifying that they apply to both securities listed on the Exchange and securities "traded" on the Exchange, which includes Nasdaq Securities. *See, e.g.,* Rule 123—NYSE Amex Equities, Exhibit 5.

14. Proposed Rule 522—NYSE Amex Equities (Limitation of Liability)

Because the Exchange will be relying on data feeds from the UTP Listing Market for the trading of Nasdaq Securities, the Exchange proposes to include a specific provision limiting liability for any loss, damage, claim or expense arising from any inaccuracy, error, delay or omission of any data or information regarding Nasdaq Securities, including, but not limited to, the collection, calculation, compilation, reporting or dissemination of any Nasdaq Security Information, as defined in Rule 522—NYSE Amex Equities, except as provided in Rules 17— and 18—NYSE Amex Equities. In addition, the Exchange also expressly disclaims making any express or implied warranties with respect to any Nasdaq Security, any Nasdaq Security Information, or the underlying index, portfolio or instrument that is the basis for determining the component securities of an ETF. *See* Exhibit 5.

Proposed Amendments to Current NYSE Amex Equities Rules

The Exchange proposes to amend certain existing NYSE Amex Equities rules to accommodate the trading of Nasdaq Securities on the Exchange.

1. Rule 2A—NYSE Amex Equities (Jurisdiction)

Rule 2A(b)—NYSE Amex Equities currently provides that the Exchange has jurisdiction to approve listings applications for securities admitted to dealings on the Exchange and may also suspend or remove such securities from trading. The Exchange proposes to amend this Rule to include the approval of the trading of Nasdaq Securities admitted to dealings on the Exchange.

2. Rule 103B—NYSE Amex Equities (Security Allocation and Reallocation)

Rule 103B—NYSE Amex Equities prescribes the criteria and procedures for the allocation and/or reallocation of NYSE Amex-listed equities securities to registered and qualified DMM Units. In particular, part IX of the Rule currently provides that NYSE Amex-listed equities securities must be allocated to posts on the Exchange Trading Floor that are exclusively designated for the trading of NYSE Amex securities.

NYSE Amex-listed equities securities currently trade on Posts 1 and 2 on the Trading Floor. However, there are not enough panels on those posts to accommodate the trading of additional hundreds of Nasdaq Securities. In order to accommodate the trading of Nasdaq Securities, the Exchange needs to be able to trade NYSE Amex-listed and Nasdaq Securities on additional posts.

The Exchange therefore proposes to amend Rule 103B—NYSE Amex Equities to permit NYSE Amex-listed securities and securities admitted to dealings on the Exchange on a UTP basis to trade on posts throughout the Trading Floor. To prevent any confusion that could arise among members trading

[41] When acting in the capacity of a market maker for a Nasdaq Security, a DMM Unit is exempt from FINRA's OATS requirements. *See* FINRA Rule 7410(j).

both NYSE-listed and NYSE Amex-listed or traded securities, which trade under different rules, proposed Rule 103B(IX) would provide that NYSE Amex-listed and/or traded (*i.e.* Nasdaq Securities) securities shall only be assigned to panels designated for the trading of such securities.

A DMM Unit that is registered to trade both NYSE and NYSE Amex-listed securities, as well as Nasdaq Securities, could trade these securities at the same post. However, DMM Unit staff would not be permitted to simultaneously trade both NYSE and NYSE Amex/Nasdaq securities, and the DMM Unit would need to commit staff to trade NYSE listed securities separate from staff committed to trade NYSE Amex listed or traded securities at any given time during the trading day. Intraday staff moves between panels would be permitted, however.

Proposed Amendments to Non-NYSE Amex Equities Rule 476A

Finally, the Exchange proposes to amend Non-NYSE Amex Equities Rule 476A Part 1A to include certain of the proposed NYSE Amex Equities Rule 500 Series in the Exchange's Minor Rule Violation Plan. Included are:

- Rule 502—NYSE Amex Equities prohibition on making a bid, offer or transaction, or routing an order, for Nasdaq Securities on or from Exchange systems before 9:30 a.m. or after the close of the Off-Hours Trading session.
- Rule 504(b)(5)—NYSE Amex Equities requirement for a DMM Unit registered in a Nasdaq Security that is an Exchange Traded Fund to report the listed concentration measures.
- Rule 504(b)(6)—NYSE Amex Equities requirement to commit staff for the trading of NYSE-listed securities separate from that for the trading of Exchange-listed securities and/or Nasdaq Securities and prohibition on trading NYSE-listed securities together with Exchange-listed securities and/or Nasdaq Securities at the same time.
- Rule 508(a)(2)—NYSE Amex Equities requirement for a DMM Unit to open trading in Nasdaq Securities at 9:30 a.m. or as soon thereafter as possible.
- Rule 508(b)(2)—NYSE Amex Equities requirements for closing a Nasdaq Security in a manual or slow market.
- Rule 509(a)—NYSE Amex Equities requirements for DMM Units.
- Rule 509(b)—NYSE Amex Equities requirements for DMM communications from the Floor.
- Rule 510(c)—NYSE Amex Equities requirements for dissemination and distribution of information for Nasdaq Securities that are derivative securities products.
- Rules 513— and 514—NYSE Amex Equities prohibitions on proprietary trading ahead of customer orders.
- Rule 516—NYSE Amex Equities requirements for reporting and recordkeeping of transactions in Nasdaq Securities.
- Rule 518—NYSE Amex Equities requirements for clearance and settlement of transactions in Nasdaq Securities.

Violations of these Rules will be subject to the fine schedule in Rule 476A. For individuals, first offenses may be charged $500.00, second offenses may be charged $1,000.00, and subsequent offenses may be charged $2,500.00. For member firms, first offenses may be charged $1,000.00, second offenses may be charged $2,500.00, and subsequent offenses may be charged $5,000.00.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with, and further the objectives of, Section 6(b)(5) of the Act,[42] in that they are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule changes also support the principles of Section 11A(a)(1)[43] of the Act in that they seek to ensure the economically efficient execution of securities transactions and fair competition among brokers and dealers and among exchange markets. The proposed rule changes also support the principles of Section 12(f) of the Act, which govern the trading of securities pursuant to a grant of unlisted trading privileges consistent with the maintenance of fair and orderly markets, the protection of investors and the public interest, and the impact of extending the existing markets for such securities.

The Exchange believes that the proposed rule changes are consistent with these principles. By providing for the trading of Nasdaq Securities on the Exchange on a UTP basis, the Exchange believes its proposal will lead to the addition of liquidity to the broader market for these securities and to increased competition among the existing group of liquidity providers. The Exchange also believes that, by so doing, the proposed rule changes will encourage the additional utilization of, and interaction with, the NYSE Amex Equities market, and provide market participants with improved price discovery, increased liquidity, more competitive quotes and greater price improvement for Nasdaq Securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEAmex–2010–31 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAmex–2010–31. This file number should be included on the

[42] 15 U.S.C. 78f(b)(5).

[43] 15 U.S.C. 78k–1(a)(1).

subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–NYSEAmex–2010–31 and should be submitted on or before May 10, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[44]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–8859 Filed 4–16–10; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61894; File No. SR–NYSEArca–2010–24]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change, as Modified by Amendment No. 1, Amending Its Fee Schedule

April 13, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 1, 2010, NYSE Arca, Inc. ("NYSE Arca" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On April 9, 2010, NYSE Arca filed Amendment No. 1 to this filing. NYSE Arca has designated this proposal as one establishing or changing a member due, fee, or other charge imposed under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Schedule of Fees and Charges for Exchange Services (the "Schedule"). While changes to the Schedule pursuant to this proposal will be effective upon filing, the changes will become operative on April 1, 2010. The amended section of the Schedule is included as Exhibit 5 hereto. A copy of this filing is available on the Exchange's Web site at *http://www.nyse.com,* at the Exchange's principal office, at the Commission's Public Reference Room, and on the Commission's Web site at *http://www.sec.gov.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing changes to certain fees to improve competitiveness and encourage participation and liquidity by Customer, Firms, Broker Dealers, and Market Makers.

Lead Market Maker Rights Fee

Presently, the Exchange charges Lead Market Makers ("LMMs") a monthly rights fee for each appointed issue. Effective April 1, 2010, the Exchange will reduce the rights fee by 50% in each tier as shown below.

Average national daily customer contracts per issue	Monthly base rate
0 to 2,000	[$150] *$75*
2,001 to 5,000	[$400] *$200*
5,001 to 15,000	[$750] *$375*
15,001 to 100,000	[$1,500] *$750*
Over 100,000	[$3,000] *$1,500*

Transaction Fee Changes

The Exchange proposes to restructure certain trade related charges for non-electronic trades. These trades are executed in the Firm range (clearance account "F") and are currently billed either the Firm Facilitation rate or the Broker Dealer & Firm rate. Under the current rate schedule trades by a firm that facilitate a customer, or Firm Facilitation trades, are subject to a $0.00 rate per contract. Firm transactions not facilitating a customer are subject to a $0.25 Broker/Dealer & Firm Manual rate. Under the revised rate schedule all manual trades clearing in the Firm range will be subject to a rate of $0.18 per contract and further capped at $2,000 per issue per day, per trading participant. Firm Proprietary electronic trades will continue to be charged $0.50 per contract in non-Penny Pilot issues, $0.45 per contract for taking liquidity in Penny Pilot issues, and receive a credit of $0.25 per contract for posting liquidity in Penny Pilot issues, consistent with the current rates, but now a separate line in the Schedule.

The Exchange also proposes to introduce a Premium Tier for electronic transactions in certain Penny Pilot Issues. Electronic executions in options overlying SPY, C, BAC, QQQQ, AAPL, IWM, XLF, GLD, EEM, GE, UNG, FAZ, DIA, GDX, and USO will qualify for the Premium Tier, and will receive an additional $.05 per contract credit above the stated Post Liquidity credit. This is consistent with similar billing treatment of select symbols currently in place at Nasdaq OMX PHLX.[5]

NYSE Arca also proposes to introduce Tiered Pricing for certain high monthly volume levels in non-Premium Tier Penny Pilot issues. This new tiered pricing structure will replace the current Market Maker Post Liquidity Incentive Credit that provided Market Makers with an additional $0.01 credit

[44] 17 CFR 200.30–3(a)(12) and 200.30–3(a)(44).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] *See* Nasdaq OMX PHLX Fee Schedule dated March 26, 2010.

for posting liquidity of greater than 1,000,000 executed contracts per month and $0.05 for posting liquidity greater than 5,000,000 executed contracts per month. The Exchange also proposes to delete the accompanying footnote eight in its entirety. For each Electronic Transaction contract in these issues above 999,999 contracts per month up to 1,999,999 per month, the Customer Take Fee will be reduced by $0.05 per contract, and the Market Maker Credit will be increased by $0.05 per contract. For each Electronic Transaction contract in these issues above 1,999,999 contracts per month up to 2,999,999 per month, the Customer Take Fee will be reduced by a total of $0.10 per contract, and the Market Maker Credit will be increased by $0.10 per contract. For each Electronic Transaction contract in these issues above 2,999,999 contracts per month, the Customer Take Fee will be reduced by a total of $0.15 per contract, and the Market Maker Credit will be increased by $0.15 per contract.

Limit of Fees on Strategy Executions

In addition, NYSE Arca also proposes to make permanent the pilot program for a cap on transaction fees for Strategy Executions associated with (a) Reversals and conversions, (b) dividend spreads, (c) box spreads, (d) short stock interest spreads, (e) merger spreads, and (f) jelly rolls. The Strategy Fee Cap pilot program expired on March 1, 2010. Under the program, transactions fees were capped at $750 per transaction, and, in addition, such transaction fees for these strategies are further capped at $25,000 per month per initiating firm. This proposal is consistent with the Nasdaq OMX PHLX filing to make permanent a similar Strategy fee cap pilot program.[6] The Exchange proposes to make the pilot permanent, effective upon filing of this proposed rule change.

The Exchange also proposes, effective April 1, 2010, that Manual Broker Dealer and Firm Strategy Trades that do not reach the $750 cap be billed at a rate of $0.25 per contract. Further, the Exchange proposes to clarify that FLEX Option executions are not considered Strategy executions.

Report Fees

Finally, the Exchange proposes to reduce the fee for User Activity extracts from $0.0075 per trade to $0.002 per trade, plus development and set-up costs.

[6] *See* Securities Exchange Act Release No. 59566 (March 12, 2009), 74 FR 11793 (March 19, 2009) (SR–PHLX–2009–18).

The changes are part of the Exchange's continued effort to attract and enhance participation on the NYSE Arca options marketplace. The Exchange believes these proposed fee changes are reasonable and equitable in that they apply uniformly to all similarly situated participants on the NYSE Arca options marketplace.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Securities Exchange Act of 1934 (the "Act"),[7] in general, and Section 6(b)(4) of the Act,[8] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities. The proposed changes to the Schedule are part of the Exchange's continued effort to attract and enhance participation on the Exchange, by offering attractive rates for removing liquidity and rebates for providing liquidity to the Exchange. The proposed changes to the Schedule are equitable in that they apply uniformly to all similarly situated OTP Holders.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[9] of the Act and subparagraph (f)(2) of Rule 19b–4[10] thereunder, because it establishes a due, fee, or other charge imposed by NYSE Arca on its members.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2010–24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2010–24. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–NYSEArca–2010–24 and should be submitted on or before May 10, 2010.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(2).

[11] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–8948 Filed 4–16–10; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61887; File No. SR–NASDAQ–2010–041]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Conforming Changes to Certain Notification Requirements

April 12, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 26, 2010, The NASDAQ Stock Market LLC ("Nasdaq") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. Nasdaq has designated the proposed rule change as effecting a change described under Rule 19b–4(f)(6) under the Act,[3] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

Nasdaq proposes to modify the Listing Rules to make conforming changes to certain notification requirements.

The text of the proposed rule change is below. Proposed new language is in *italic;* proposed deletions are in [brackets].[4]

5250. Obligations for Companies Listed on The Nasdaq Stock Market

(a) No change.

(b) Obligation to Make Public Disclosure

(1) No change.

(2) As set forth in Rule 5810(b), a Company that receives a notification of deficiency from Nasdaq is required to make a public announcement by filing a Form 8–K, where required by SEC rules, or by issuing a press release disclosing receipt of the notification and the Rule(s) upon which the deficiency is based. However, note that in the case of a deficiency related to the requirement to file a periodic report contained in Rule 5250(c)(1) or (2), the Company is required to make the public announcement by issuing a press release. As described in Rule 5250(b)(1) and IM–5250–1, [notice to the] *the Company must notify Nasdaq's* MarketWatch Department [must be made] *about the announcement* through the electronic disclosure submission system available at www.nasdaq.net, *except in emergency situations when notification may instead be provided by telephone or facsimile. If the public announcement is made during Nasdaq market hours, the Company must notify MarketWatch* at least ten minutes prior to the [public] announcement. *If the public announcement is made outside of Nasdaq market hours, the Company must notify MarketWatch of the announcement prior to 6:50 a.m. ET.*

(c)–(f) No change.

* * * * *

5810. Notification of Deficiency by the Listing Qualifications Department

When the Listing Qualifications Department determines that a Company does not meet a listing standard set forth in the Rule 5000 Series, it will immediately notify the Company of the deficiency. As explained in more detail below, deficiency notifications are of four types:

(1)–(4) No change.

Notifications of deficiencies that allow for submission of a compliance plan or an automatic cure or compliance period may result, after review of the compliance plan or expiration of the cure or compliance period, in issuance of a Staff Delisting Determination or a Public Reprimand Letter.

(a) No change.

(b) Company Disclosure Obligations

A Company that receives a notification of deficiency, Staff Delisting Determination, or Public Reprimand Letter is required to make a public announcement disclosing receipt of the notification and the Rule(s) upon which the deficiency is based. A Company that receives a notification of deficiency or Staff Delisting Determination related to the requirement to file a periodic report contained in Rule 5250(c)(1) or (2) is required to make the public announcement by issuing a press release disclosing receipt of the notification and the Rule(s) upon which the deficiency is based, in addition to filing any Form 8–K required by SEC rules. In all other cases, the Company may make the public announcement either by filing a Form 8–K, where required by SEC rules, or by issuing a press release. [Before release of the public announcement, Companies must provide a copy of the announcement to Nasdaq's MarketWatch Department.] As described in Rule 5250(b)(1) and IM–5250–1, [notice to the] *the Company must notify Nasdaq's* MarketWatch Department [must be made] *about the announcement* through the electronic disclosure submission system available at www.nasdaq.net, *except in emergency situations when notification may instead be provided by telephone or facsimile. If the public announcement is made during Nasdaq market hours, the Company must notify MarketWatch* at least ten minutes prior to the [public] announcement. *If the public announcement is made outside of Nasdaq market hours, the Company must notify MarketWatch of the announcement prior to 6:50 a.m. ET.* The Company should make the public announcement as promptly as possible but not more than four business days following receipt of the notification.

(c)–(d) No change.

* * * * *

5840. Adjudicatory Process: General Information

(a)–(j) No change.

(k) Disclosure of Public Reprimand Letter

A Company that receives an Adjudicatory Body Decision that serves as a Public Reprimand Letter must make a public announcement by filing a Form 8–K, where required by SEC rules, or by issuing a press release disclosing the receipt of the Decision, including the Rule(s) upon which the Decision was based. [Prior to the release of the public announcement, the Company must provide such disclosure to Nasdaq's MarketWatch Department.] As described in Rule 5250(b)(1) and IM–5250–1, [notice to the] *the Company must notify Nasdaq's* MarketWatch Department [must be made] *about the announcement* through the electronic disclosure submission system available at www.nasdaq.net, *except in emergency situations when notification may instead be provided by telephone or facsimile. If the public announcement is made during Nasdaq market hours, the Company must notify MarketWatch* at least ten minutes prior to the [public] announcement. *If the public announcement is made outside of Nasdaq market hours, the Company must notify MarketWatch of the announcement prior to 6:50 a.m. ET.* The *Company should make the* public announcement [should be made] as

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] Changes are marked to the rule text that appears in the electronic manual of Nasdaq found at *http://nasdaq.cchwallstreet.com.*

promptly as possible[,] but not more than four business days following receipt of the Decision.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq recently adopted changes to certain of its press release requirements for Nasdaq-listed companies (the "Press Release Filing").[5] Subsequent to Nasdaq's filing and the Commission's publication of this proposal,[6] Nasdaq made an immediately effective change to its rules to clarify when listed companies must provide notification to Nasdaq of material information disclosed outside of market hours.[7] As revised, when the material information is made public outside of Nasdaq market hours, Nasdaq companies must provide notification of the information to MarketWatch by 6:50 a.m. ET. Nasdaq proposes to make conforming changes to the rules modified in the Press Release Filing, such that Rules 5250(b)(2), 5810(b) and 5840(k) would each specify that if a required public announcement is made during market hours, the company must notify Nasdaq's MarketWatch Department at least ten minutes prior to making the announcement to the public; otherwise the company must notify the MarketWatch Department prior to 6:50 am ET. Nasdaq also proposes to clarify that companies are not required to use the electronic disclosure submission system to notify MarketWatch in emergency situations, when notification may instead be provided by telephone or facsimile.[8] Finally, Nasdaq proposes to make other non-substantive changes to these rules so that they each use consistent language.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[9] in general and with Sections 6(b)(5) of the Act,[10] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed change will conform Nasdaq's notification requirements in the rules amended in the Press Release Filing with Nasdaq's notification requirements for the disclosure of material information, thereby reducing confusion among listed companies and investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[13] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay.

The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because the proposed rule change would merely conform Rules 5250(b)(2), 5810(b) and 5840(k) to the notification requirements when companies release material information outside of market hours in Nasdaq's other rules,[15] thereby reducing company and investor confusion. As such, the Commission believes that the proposed rule change raises no new regulatory issues. Additionally, Nasdaq's clarification that in emergencies, companies are not required to notify MarketWatch through the electronic disclosure system but may do so via telephone or facsimile aligns the rules to the existing requirements of Nasdaq Rule 5250(b)(1) and IM–5250–1, further reducing confusion for companies.[16] For these reasons, the Commission designates that the proposed rule change become operative immediately upon filing.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing,

[5] Securities Exchange Act Release No. 61713 (March 15, 2010), 75 FR 13629 (March 22, 2010) (SR–NASDAQ–2010–006).

[6] Securities Exchange Act Release No. 61461 (February 1, 2010), 75 FR 6241 (February 8, 2010) (SR–NASDAQ–2010–006).

[7] Securities Exchange Act Release No. 61521 (February 16, 2010), 75 FR 8156 (February 23, 2010) (SR–NASDAQ–2010–008).

[8] IM–5250–1 already provides that companies do not have to use the electronic disclosure submission system in an emergency situation and provides examples of emergency situations, such as the lack of computer or internet access, technical problems, and cases where no draft disclosure document is available.

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). Pursuant to Rule 19b–4(f)(6)(iii) under the Act, the Exchange is required to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] *See* Nasdaq Rule 5250(b)(1) and IM–5250–1.

[16] *See supra* note 8.

[17] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File No. SR–NASDAQ–2010–041 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NASDAQ–2010–041. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of NASDAQ. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NASDAQ–2010–041 and should be submitted on or before May 10, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–8947 Filed 4–16–10; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61895; File No. SR–NYSEArca–2010–28]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of a Proposed Rule Change Amending Its Schedule of Fees

April 13, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 12, 2010, NYSE Arca, Inc. ("NYSE Arca" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NYSE Arca. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot program regarding a cap on transaction fees for strategy executions. A copy of this filing is available on the Exchange's Web site at *http://www.nyse.com,* at the Exchange's principal office, at the Commission's Public Reference Room, and on the Commission's Web site at *http://www.sec.gov.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NYSE Arca proposes to extend the pilot program regarding a cap on transaction fees for strategy executions ("Program"). Under this Program, strategy executions are capped at $750 per transaction, and, in addition, transaction fees for these strategies are further capped at $25,000 per month per initiating firm. This Program previously expired on March 1, 2010. Extending this Program retroactively from March 1, 2010 through April 1, 2010 facilitates consistent treatment with respect to fees for strategy executions.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[3] of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5)[4] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system. In addition, the proposed extension of the Program is reasonable in that the fees are equitable as they apply uniformly to all similarly situated OTP Holders.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(5).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2010–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2010–28. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of NYSE Arca. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–NYSEArca–2010–28 and should be submitted on or before May 10, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[5]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–8946 Filed 4–16–10; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61883; File No. SR–BATS–2010–007]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Fees for Use of BATS Exchange, Inc.

April 9, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 31, 2010, BATS Exchange, Inc. (the "Exchange" or "BATS") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. BATS has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify its fee schedule applicable to Members[5] of the Exchange pursuant to BATS Rules 15.1(a) and (c). While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on April 1, 2010.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com,* on the Commission's Web site at *http://www.sec.gov,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify its fee schedule applicable to use of the Exchange effective April 1, 2010, in order to: (i) Increase the fee charged by the Exchange for its "CYCLE" and "RECYCLE" routing strategies from $0.0027 per share to $0.0028 per share; (ii) amend the fees for certain destination specific routing options to continue to offer a "one under" pricing model; (iii) adopt pricing for "BATS + DART Destination Specific Orders"; and (iv) make other technical changes to the fee schedule.

(i) Increase in Routing Fees for "CYCLE" and "RECYCLE" Routing

Based on increased fees at various market centers to remove liquidity, the Exchange proposes to modify the fee charged by the Exchange for its "CYCLE" and "RECYCLE" routing strategies from $0.0027 per share to $0.0028 per share. To be consistent with this change, the Exchange proposes to charge 0.28%, rather than 0.27%, of the total dollar value of the execution for any security (all Tapes) priced under $1.00 per share that is routed away from the Exchange through CYCLE or RECYCLE.

(ii) One Under Pricing for Destination Specific Orders

The Exchange has previously provided a discounted price fee for Destination Specific Orders routed to certain of the largest market centers measured by volume (NYSE, NYSE Arca and NASDAQ), which, in each instance has been $0.0001 less per share for orders routed to such market centers by the Exchange than such market centers currently charge for removing liquidity (referred to by the Exchange as "One Under" pricing). Based on changes in

[5] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A Member is any registered broker or dealer that has been admitted to membership in the Exchange.

pricing at such market centers, BATS is proposing various changes to its prices for Destination Specific Orders to align its fees so they are $0.0001 less per share for orders routed to such market centers as of April 1, 2010. Specifically, because NASDAQ has eliminated the distinction in its fees between Tape A, B, and C securities the Exchange proposes to eliminate that same distinction for BATS + NASDAQ Destination Specific Orders. Thus, the Exchange proposes to normalize the fee charged for BATS + NASDAQ Destination Specific Orders executed at NASDAQ at $0.0029 per share. Also, based on a change to pricing at NYSE Arca, the Exchange proposes to increase the charge from $0.0027 per share to $0.0028 per share for BATS + NYSE Arca Destination Specific Orders executed at NYSE Arca in Tape A and C securities. The Exchange will retain the fee of $0.0027 per share for BATS + NYSE Arca Destination Specific Orders executed at NYSE Arca in Tape B securities. Each of the changes described above will result in the Exchange charging $0.0001 less per share for orders routed to certain market centers as Destination Specific Orders.

(iii) Pricing for BATS + DART Destination Specific Orders

Effective April 1, 2010, the Exchange will offer functionality that will permit Users to designate orders to route to various Alternative Trading Systems selected by the Exchange after first being exposed to the BATS Book (a "BATS + DART Destination Specific Order"). In conjunction with this new functionality, the Exchange is proposing to amend the fee schedule to include pricing for BATS + DART Destination Specific Orders. The Exchange currently offers DART routing as part of its general best execution routing. Consistent with the current pricing for the DART best execution routing functionality, the Exchange proposes to charge $0.0020 per share for a BATS + DART Destination Specific Order executed by an Alternative Trading System.

(iv) Technical Changes to Fee Schedule

The Exchange proposes to correct a typographical error on the fee schedule. Also, the Exchange proposes to add a clarifying parenthetical to its description of physical connection charges, which are charged based on "pairs." As it does within the Equities Pricing/Port Fees section of the fee schedule, the Exchange proposes to make clear that a pair is comprised of one port at site of the Exchange's primary data center and one port at the site of the Exchange's secondary data center.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[6] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[7] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. In addition, the Exchange believes that the proposed rates are equitable in that they apply uniformly to all Members.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has been designated as a fee change pursuant to Section 19(b)(3)(A)(ii) of the Act[8] and Rule 19b–4(f)(2) thereunder,[9] because it establishes or changes a due, fee or other charge imposed on members by the Exchange. Accordingly, the proposal is effective upon filing with the Commission.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] 17 CFR 240.19b–4(f)(2).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–BATS–2010–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2010–007. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2010–007 and should be submitted on or before May 10, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–8860 Filed 4–16–10; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Privacy Act of 1974: System of Records

AGENCY: Bureau of Transportation Statistics, DOT.

ACTION: Notice to establish a system of records.

SUMMARY: DOT intends to establish a system of records under the Privacy Act of 1974.

DATES: *Effective Date:* June 1, 2010. If no comments are received, the proposal will become effective on the above date. If comments are received, the comments will be considered and, where adopted, the documents will be republished with changes.

ADDRESSES: Send comments to: Habib Azarsina, Departmental Privacy Officer, S–80, United States Department of Transportation, Office of the Secretary of Transportation, 1200 New Jersey Ave., SE., Washington, DC 20590, or *habib.azarsina@dot.gov*.

FOR FURTHER INFORMATION CONTACT: Habib Azarsina, Departmental Privacy Officer, S–80, United States Department of Transportation, Office of the Secretary of Transportation, 1200 New Jersey Ave., SE., Washington, DC 20590, telephone 202–366–1965 or *habib.azarsina@dot.gov*

SUPPLEMENTARY INFORMATION: The Department of Transportation system of records notice subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, has been published in the **Federal Register** and is available from the above mentioned address.

SYSTEM NUMBER: DOT/ALL 21

SYSTEM NAME:

Close Call Confidentiality Reporting System (C^{3}RS).

SECURITY CLASSIFICATION:

Unclassified, sensitive.

SYSTEM LOCATION:

The system is housed on a stand-alone desktop in the C^{3}RS secure room located in room E36–311 at the Bureau of Transportation Statistics, United States Department of Transportation, 1200 New Jersey Ave., SE., Washington, DC 20590.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM OF RECORDS:

Railroad employees who report close calls to BTS, either by telephone or mail, as part of a five-year demonstration/research project are covered by this system of records. These individuals are employees of three rail carriers participating in the C^{3}RS demonstration project. The rail carriers are: Union Pacific Railroad, Canadian Pacific Railroad, and New Jersey Transit.

The C^{3}RS demonstration project is a research effort to improve safety by using information from close call events to prevent serious accidents in the rail industry. A close call or near miss is an unsafe event with the potential for a more serious incident resulting in greater injury to personnel or damage to equipment above FRA's reportable threshold level.

Employees can report about a near miss event that happened to their crew or an event they witnessed about another crew (third party reporting). In the case of third party reporting, the employee does not provide any PII information on those involved in the reported close call. Reporting employees are not allowed to make anonymous close call reports.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in the C^{3}RS system contain information pertinent to an actual close call event submitted to BTS in a C^{3}RS report. The following PII data elements are included in every C^{3}RS report accepted into the system: The reporting employee's name, age, job classification, home address, and home and mobile telephone number(s) (if available).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), which was enacted August 10, 2005 as Public Law 109–59.

PURPOSES:

The C^{3}RS collects name, home address, and telephone number(s) of railroad employees reporting close calls events to BTS. Qualified BTS/C^{3}RS staff will use the contact information as follows:

- The employee's name and home telephone number will be used to generate and give the employee his/her unique confirmation number, upon receiving the employee's close call phone message;
- The employee's name and home telephone number will be used to notify the employee that BTS has received the employee's C^{3}RS report and to schedule an interview time with the employee for further discussion of the close call incident;
- The employee's name and home telephone number will be used to initiate the close call interview;
- The employee's name and home address will be used to create and mail out a confirmation/rejection letter notifying the employee about the status of his/her close call report; and
- The employee's job classification will be used to understand the employee's role in the close call incident.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

BTS does not share PII information collected for the C^{3}RS study with other entities. A primary goal of the C^{3}RS is to protect the identity of any employee who reports a close call incident to BTS. Reports collected and maintained in the C^{3}RS are protected from disclosure as provided in the BTS confidentiality statute (49 U.S.C. 111(k)) and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The C^{3}RS Demonstration Project stores all data in an electronic database in a stand-alone desktop computer attached to a non-network printer. The computer and printer are in a secure data collection room. Hard-copy documents (work papers) are stored in the secure room and shredded after project completion.

RETRIEVABILITY:

Records are retrieved from the C^{3}RS database by confirmation number, which uniquely identifies individual reports and by employee identification numbers.

SAFEGUARDS:

All the information BTS obtains, including the PII data, is kept in a secure room in the Department of Transportation Headquarters building in Washington, DC. Only members of the C^{3}RS team who have taken confidentiality training and signed a non-disclosure agreement have access to

[10] 17 CFR 200.30–3(a)(12).

the secure room. The door of the secure room is kept closed during work hours and kept locked when the room is not in use. The stand-alone workstation that contains the database is password protected. All paper working documents are stored in the secure room and shredded immediately after case completion.

RETENTION AND DISPOSAL:

The C3RS project is a five-year research/feasibility study subject to availability of funds. BTS will retain the entire C3RS database for up to ten years after completion of the project (*i.e.*, up to fifteen years total). The system is currently unscheduled; pending approval of a retention schedule by the National Archives and Records Administration (NARA), the records must be kept indefinitely. The retention periods that will be proposed to NARA are as follows: upon project completion, all PII data fields will be destroyed, and all non-PII data will be retired to the Federal Records Center (FRC). The non-PII data will be destroyed 10 years after completion of the study.

SYSTEM MANAGER(S) AND ADDRESS:

C3RS Data Collection Officer, Bureau of Transportation Statistics, Research & Innovative Technology Administration, Department of Transportation, 1200 New Jersey Ave., SE., RTS–31, Washington, DC 20590.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether their information is contained in this system should address written inquiries to: C3RS Data Collection Officer, Bureau of Transportation Statistics, Research & Innovative Technology Administration, Department of Transportation, 1200 New Jersey Ave., SE., RTS–31, Washington, DC 20590. Requests should include name, address and telephone number and a description of the request.

RECORD ACCESS PROCEDURES:

Same as "Notification Procedure."

CONTESTING RECORD PROCEDURES:

Same as "Notification Procedure."

RECORD SOURCE CATEGORIES:

Information is obtained directly from the individuals who report close call incidents to BTS.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: April 13, 2010.

Habib Azarsina,

Departmental Privacy Officer, 202–366–1965.

[FR Doc. 2010–8908 Filed 4–16–10; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Intent To Prepare an Environmental Impact Statement for Expansion of Light Rail Transit Service From Glassboro, NJ to Camden, NJ

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of Intent to prepare an Environmental Impact Statement.

SUMMARY: FTA, in coordination with the Delaware River Port Authority (DRPA)/Port Authority Transit Corporation (PATCO), is issuing this Notice of Intent (NOI) to advise the public that it proposes to prepare an Environmental Impact Statement (EIS) to assess the potential environmental impacts associated with the construction and operation of the Glassboro-Camden Line (GCL) light rail system, as well as assess and document a No-Action Alternative and a Transportation System Management (TSM) Alternative. The proposed GCL system is approximately 18 miles long and would operate between the Borough of Glassboro in Gloucester County and the City of Camden in Camden County along, and primarily within, the existing Conrail railroad right-of-way. Light Rail technology along this alignment was selected as the Recommended Alternative based on a two-year Alternatives Analysis completed by DRPA/PATCO in 2009.

FTA is issuing this notice to solicit public and agency input regarding the scope of the EIS and to advise the public and agencies that outreach activities conducted by DRPA/PATCO and its representatives will be considered in the preparation of the EIS. FTA is the lead federal agency for the environmental review, with DRPA/PATCO as the joint lead agency.

DATES: Written comments on the scope of the EIS, including the project's purpose and need, the alternatives to be considered, and the impacts to be evaluated should be sent to DRPA on or before June 10, 2010. *See* **ADDRESSES** below for the address to which written comments may be sent. Oral comments on the scope of the EIS can be made at Public Scoping Meetings on the following dates:

- Thursday, May 6, 2010 at Camden County College—Camden Technology Center, 200 North Broadway, Camden, NJ 08102 from 5:30 to 8:30 p.m.
- Tuesday, May 11, 2010 at Rowan University (Henry M. Rowan Bldg.), 201 Mullica Hill Road, Glassboro, NJ 08028 from 1:30 to 4:30 p.m.
- Tuesday, May 11, 2010 at Rowan University (Henry M. Rowan Bldg.), 201 Mullica Hill Road, Glassboro, NJ 08028 from 5:30 to 8:30 p.m.

An informational session explaining the proposed project will occur during the first hour of each meeting, followed by the opportunity for the public and/or agency representatives to provide oral comments on the scope of the EIS. Those individuals wishing to speak at the meetings are required to register at the particular meeting location on the day of that meeting. Anyone who requires special assistance at a scoping meeting should contact Ms. Victoria Malaszecki, Public Involvement Coordinator at (856) 223–0800, via e-mail at *publicinvolvement@GlassboroCamdenLine.com,* or at the address listed below at least 3 days prior to the meeting.

An agency scoping meeting will be held on Monday, May 3, 2010 at 2 p.m., at DRPA, One Port Center, 2 Riverside Drive, Camden, NJ. Representatives from federal, state, regional, tribal, and local agencies that may have an interest in the project will be invited to serve as either participating or cooperating agencies.

ADDRESSES: Comments will be accepted orally at the public scoping meetings, or they may be sent to Ms. Victoria Malaszecki, Public Outreach Liaison, Envision Consultants, Ltd. by mail at PO Box 536, Mullica Hill, NJ 08062, by fax (856)–223–8886, or by e-mail at *publicinvolvement@GlassboroCamdenLine.com*. The addresses of the scoping meetings are listed above under **DATES**.

FOR FURTHER INFORMATION CONTACT: Either Mr. Keith Lynch, Project Advisor, Federal Transit Administration, 1716 Market Street, Suite 500, Philadelphia, PA 19103 or (215) 656–7056; or Mr. Michael Venuto, Project Manager, Delaware River Port Authority, One Port Center, 2 Riverside Drive, Camden, NJ 08101 or (856) 968–2079.

Additional project information and scoping materials will be available at the meetings and on the project Web site (*http://www.GlassboroCamdenLine.com*).

SUPPLEMENTARY INFORMATION:

I: Scoping

FTA and DRPA/PATCO will undertake a scoping process that will allow the public and interested agencies to comment on the scope of the environmental review process. Scoping is the process of determining the scope, focus, and content of an EIS. NEPA scoping has specific objectives, identifying the significant issues that

will be examined in detail during the EIS, while simultaneously limiting consideration and development of issues that are not truly significant. FTA and DRPA/PATCO invite all interested individuals and organizations, public agencies, and Native American tribes to comment on the scope of the Draft EIS. To facilitate public and agency comment, a Draft Scoping Document will be prepared for review. Included in this document will be draft descriptions of: The purpose and need for the project; the alternatives to be studied; the impacts to be assessed; and the public outreach and agency coordination process.

II: Proposed Purpose and Need

The purpose of this project is to improve transit service along the Glassboro to Camden corridor in southern New Jersey with a focus on increasing mobility and improving links between the established communities and activity centers.

The Glassboro to Camden corridor is characterized by older, densely populated communities that developed along the rail line, as well as by major employment and activity centers including universities, medical centers and other institutions. However, connections between these activity centers and the people who access them are not efficient and travel along the corridor is difficult. With regard to transit service especially, the corridor lacks competitive and reliable transit options between the major communities and activity centers.

Trips along the corridor are primarily made by car. Major roadways experience congestion during peak hours, and even greater travel demands are predicted for the future in Gloucester and Camden counties, associated with growth in population and employment. This growth will contribute to continued increases in vehicle miles of travel, air pollutants and greenhouse gases, and travel times. In addition, this auto dependence has contributed to and continues to encourage development "sprawl" into open space and agricultural land, requiring new supporting infrastructure, and does not encourage growth in the established communities as promoted by state and local "Smart Growth" initiatives.

The proposed 18-mile GCL traverses established communities and would provide a new reliable transit system competitive with auto travel, linking activity centers, employment destinations and established residential areas. This reliability and competitiveness would encourage a modal shift from auto to transit, and contribute to reduced congestion, vehicle miles of travel, air pollutants and greenhouse gases, and travel times. Aligning the GCL with the existing Conrail railroad right-of-way would minimize property acquisition and take advantage of an underutilized transportation corridor. Moreover, its location amid established communities would encourage growth and economic development consistent with "Smart Growth" programs and policies at the local, State, and regional level.

III: Proposed Alternatives

The alternatives expected to be included in the EIS include:

No Action Alternative: The No Action Alternative represents future conditions in the EIS analysis year of 2035 without the GCL Project. The No Action Alternative includes the existing transit and transportation system in southern New Jersey plus planned improvements for which the need, commitment, financing and public and political support have been identified, and which may reasonably be expected to be implemented. This Alternative is included in the Draft EIS as a means of comparing and evaluating the impacts and benefits of the GCL alternatives.

Transportation System Management (TSM) Alternative: The TSM alternative consists of enhancements and upgrades to the existing transportation system to address some of the needs and purpose of the project at less capital cost. These upgrades can include bus route restructuring and headway reductions, express and limited-stop service, intersection improvements, and other limited infrastructure improvements that enhance the transportation system. The specific combination of improvements to be incorporated into the TSM will be developed during the EIS process.

Light Rail Alternative: Based on the results of the 2009 Alternatives Analysis of transit options, light rail service from Glassboro to Camden was selected as the Recommended Alternative to provide expanded transit service in Gloucester and Camden counties, New Jersey. This alternative will be the focus of the Draft EIS assessment and documentation.

The Light Rail Alternative would traverse the communities of Glassboro, Pitman, Sewell, Mantua Township, Deptford Township, Wenonah, Woodbury Heights, Woodbury, Westville, Brooklawn, Gloucester City, and Camden. The new line would primarily run along Conrail's freight alignment, which is roughly parallel to Woodbury-Glassboro Road and NJ Route 45. The northern segment in Camden would follow a new right-of-way adjacent to I–676 before entering an in-street alignment to reach Walter Rand Transportation Center where riders could transfer to the PATCO Lindenwold Line and the NJ TRANSIT River Line.

The Light Rail Alternative would use diesel-powered light rail vehicles, operating on new dedicated tracks and/or sharing portions of Conrail track with temporal separation. Approximately fourteen (14) new stations would be located along the alignment.

IV: Probable Effects

FTA and DRPA/PATCO will evaluate both project-specific as well as indirect and cumulative effects to the existing physical, social, economic and environmental setting in which the GCL will be located. The permanent, long-term effects to the region could include effects to traffic and transportation; land use and socioeconomics; visual character and aesthetics; noise and vibration; historical and archaeological resources; community impacts; and natural resources. Temporary impacts during construction of the project could include effects to air quality; noise and vibration; natural resources; and contaminated and hazardous materials.

The analysis will be undertaken in conformity with NEPA, Council on Environmental Quality regulations, FTA guidance and relevant environmental guidelines, Section 106 of the National Historic Preservation Act, section 4(f) of the DOT Act, Executive Order 12898 regarding minority and low-income populations, the Clean Water Act and the Clean Air Act of 1970, along with other applicable Federal and State regulations. Opportunities for comment on the potential effects to be studied will be provided to the public, and comments received will be considered in the development of the final scope and content of the environmental documents.

V: Public and Agency Involvement Procedures

The regulations implementing NEPA, as well as provisions of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), call for public involvement in the EIS process. In accordance with Section 6002 of SAFETEA–LU, FTA and DRPA/PATCO will: (1) Extend an invitation to other Federal and non-Federal agencies and Native American Tribes that may have an interest in the proposed project to become participating agencies (any interested party that does not receive an

invitation to become a participating agency can notify any of the contact persons listed earlier in this NOI); (2) Provide opportunity for involvement by participating agencies and the public to help define the purpose and need for the proposed project, as well as the range of alternatives for consideration in the EIS; and (3) Establish a plan for coordinating public and agency participation in, and comment on, the environmental review process.

A Public Involvement Plan and an Agency Coordination Plan will be developed outlining public and agency involvement for the project. These will be available on the project Web site or through written request. Opportunities for comment will be provided throughout the EIS process, including public and agency meetings, the project Web site, a mailing address, and a phone information line. Comments received from any of these sources will be considered in the development of the final scope and content of the environmental documents.

VI. Summary/Next Steps

With the publication of this NOI, the scoping process for the project begins. After the publication of the Draft Scoping Document, a public comment period will begin, allowing the public to offer input on the scope of the EIS until June 10, 2010. Public comments will be received through those methods explained earlier in this NOI and will be incorporated into a Final Scoping Document. This document will detail the scope of the EIS and the potential environmental effects that will be considered during the study period. After the completion of the Draft EIS, another public commenting period will allow for input on the EIS, and these comments will be incorporated into the Final EIS report before publication.

Issued on: April 12, 2010.

Letitia A. Thompson,

FTA Region III Administrator.

[FR Doc. 2010–8965 Filed 4–16–10; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Tenth Meeting: RTCA Special Committee 214: Working Group 78: Standards for Air Traffic Data Communication Services

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of RTCA Special Committee 214: Working Group 78: Standards for Air Traffic Data Communication Services.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the RTCA Special Committee 214: Working Group 78: Standards for Air Traffic Data Communication Services.

DATES: The meeting will be held May 3–7, 2010 from 9 a.m.–5 p.m.

ADDRESS: The meeting will be held at Palma de Majorca, SPAIN, Air Europa Lineas Aereas, S.A., Centro Empresarial Globalia, Ctra. Arenal—Llucmajor, km 21,5, Poligono Industrial Son Noguera, C.P: 07620 Mallorca, Illes Balears, SPAIN.

Hosts: Mr. Juan Rossello—*jrossello@air-europa.com* and Capt. Jordi Manzano *jordi.manzano@air-europa.com.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a RTCA Special Committee 214: Working Group 78: Standards for Air Traffic Data Communication Services meeting. The agenda will include:

Additional Information

Additional information and all the documents to be considered can be found in the Web site *http://www.faa.gov/go/SC214.*

Meeting Objectives

- Approval new Sub-groups, Organization & Process, review preliminary activities
- Coordination with SC–217/WG–44 and SC–186/WG–51
- Agree on approach for Oceanic/Continental Integration
- Review of Position Papers
- Progress on D–RVR & D–HZWX Service assessment
- Review and Update the work plan as required

Agenda

Day 1 (Monday 3rd May 2010)

09h00–12h30: Plenary Session
- Welcome/Introductions/Administrative Remarks
- Approval of the Agenda
- Approval of the Summary of Plenary 9
- Review Action Item Status
- Coordination Activities
- Briefing from SC–217/WG–44 (D–TAXI, Airport Data Base)
- Briefing from SC–186/WG–51 (CPDLC support for Interval Management)
- Review of the work so far
- SPR & INT documents version H
- SC–214/WG–78 TORs and Work Plan
- Review of Position Papers
- Oceanic/Continental Integration Position paper
- Seamless ATS Datalink (Airbus)
- Security paper (FAA)

13h30–17h00: Plenary Session
- New Sub-groups organization
- Announcement of Sub-group Chairs
- Approval of Organization & Process, review preliminary activities
- Configuration Sub-group (CSG–SG)
- Validation Sub-group (VSG–SG)
- VDL Sub-group (VDL–SG)
- Approval of Sub-group Meeting Objectives

Day 2 (Tuesday 4th Marc 2010) 9h00–17h00: Sub-Group Sessions

Day 3 (Wednesday 5th May 2010) 9h00–17h00: Sub-Group Sessions

Day 4 (Thursday 6th May 2010 9h00–17h00): Plenary Session

- Configuration Sub-Group Report & Assignment of Action Items
- Validation Sub-group Report & Assignment of Action Items
- VDL Sub-group Report & Assignment of Action Items
- Review Dates and Locations Upcoming Meetings
- Any Other Business
- Adjourn

Day 5 (Friday 7th May 2010): Sub-Group Sessions

9h00–16H00: Sub-Group Sessions

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC on April 12, 2010.

Francisco Estrada C.,

RTCA Advisory Committee.

[FR Doc. 2010–8849 Filed 4–16–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0041; Notice 1]

Fuji Heavy Industries USA, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

Fuji Heavy Industries USA, Inc. (Fuji), on behalf of Subaru of America, Inc.,

and Fuji Heavy Industries, Ltd., has determined that the front passenger airbag suppression status telltale in some 2010 Subaru Legacy passenger car and Outback multipurpose vehicle models, manufactured from the start of their 2010 model year production [1] through June 30, 2009, did not comply with paragraph S19.2.2 of 49 CFR 571.208, Federal Motor Vehicle Safety Standard (FMVSS) No. 208, *Occupant Crash Protection.* Fuji estimates that less than 1 percent (0.8%) or about 27 out of a total of 3,405 vehicles potentially involved have the noncompliance.[2] Fuji has filed an appropriate report pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports.*

Pursuant to 49 U.S.C. 30118(d) and 30120(h), Fuji has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Fuji's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Fuji estimated that 3,405 [3] 2010 Legacy passenger cars and Outback multipurpose passenger vehicles, produced at the Company's Subaru Automotive Indiana plant between the start of model year 2010 production through June 30, 2009, are involved. Fuji also estimated that 0.8% of those 3,405 have the subject noncompliance.

Paragraph S19.2.2 of FMVSS No. 208 requires:

S19.2.2 The vehicle shall be equipped with at least one telltale which emits light whenever the passenger air bag system is deactivated and does not emit light whenever the passenger air bag system is activated, except that the telltale(s) need not illuminate when the passenger seat is unoccupied. Each telltale:

(a) Shall emit yellow light;

(b) Shall have the identifying words "PASSENGER AIR BAG OFF" or "PASS AIR BAG OFF" on the telltale or within 25 mm (1.0 in) of the telltale; and

(c) Shall not be combined with the readiness indicator required by S4.5.2 of this standard.

(d) Shall be located within the interior of the vehicle and forward of and above the design H-point of both the driver's and the right front passenger's seat in their forwardmost seating positions and shall not be located on or adjacent to a surface that can be used for temporary or permanent storage of objects that could obscure the telltale from either the driver's or right front passenger's view, or located where the telltale would be obscured from the driver's view if a rear-facing child restraint listed in appendix A or A–1, as appropriate, is installed in the right front passenger's seat.

(e) Shall be visible and recognizable to a driver and right front passenger during night and day when the occupants have adapted to the ambient light roadway conditions.

(f) Telltales need not be visible or recognizable when not activated.

(g) Means shall be provided for making telltales visible and recognizable to the driver and right front passenger under all driving conditions. The means for providing the required visibility may be adjustable manually or automatically, except that the telltales may not be adjustable under any driving conditions to a level that they become invisible or not recognizable to the driver and right front passenger.

(h) The telltale must not emit light except when the passenger air bag is turned off or during a bulb check upon vehicle starting.

Fuji explained that the noncompliance is that front passenger airbag suppression status telltale lamp did not illuminate as required by paragraph S19.2.2 of FMVSS No. 208. Fuji expressed the belief that the cause of the noncompliance is an open circuit in the power supply to the lamp. The Company said that "installation of the wiring harness to the multifunction display and passenger airbag suppression status telltale was routed at the instrument panel subsupplier such that tension was put on the wiring harness connector" which can cause it to come loose. To correct this problem, the Company has re-routed the wiring harness to "push" rather than "pull" on the wiring harness connector in vehicles manufactured after July 10, 2009.

The noncompliance was discovered on July 1, 2009, at the Company's Subaru Indiana plant during a quality inspection process that revealed a number of multi-function displays that did not illuminate and further inspection revealed that this also affected the front passenger airbag suppression status telltale.[4]

On July 10, 2009, Fuji completed the inspection of 5,400 of its vehicles awaiting shipment and corrected the noncompliance of 45 vehicles by "pushing tight" the harness connector. In addition, Subaru of America, Inc. notified its U.S. dealers and distributors on July 16, 2009, and included complete repair instructions for vehicles in their inventory which had not been inspected or repaired prior to shipment from the Company.

Fuji believes that the noncompliance is inconsequential to motor vehicle safety. Fuji argues that:

Based on the inspection of approximately 5,400 vehicles still at Subaru Automotive Indiana and a finding that the wiring harness connector to the front passenger airbag suppression status telltale or other multi-function display had been loose on 45 vehicles, Subaru has determined that the expected occurrence rate is about 0.8% [less than one percent].

[Subaru] * * * has determined that 3,405 vehicles were shipped to dealers prior to the discovery of this problem. Using the above frequency rate,

* * * [the Company] expect that only about 27 vehicles will have a noncompliance with FMVSS 208.

All other aspects of the front passenger advanced airbag suppression system will continue to function properly.

Since Subaru has both an OFF and ON indication in the suppression telltale, a complete absence of illumination is a warning that the lamp is not functioning. Since power to the telltale is also power to the multi-function display, the owner will have a clear indication to quickly report a problem to a Subaru dealer.

Vibration bench testing in Japan by the [Company's] supplier revealed that no disengagement of a wiring harness connector that originally worked properly will occur during the use of vehicle.

Dealers will receive a TSB with repair instructions on July 16, 2009 for any vehicles in their inventory, which had not been inspected or repaired prior to shipment to dealers or for vehicles where the owner reports a telltale/multi-function display problem. Dealers will also be instructed to check both the telltale and display at the first scheduled service (at 3,750 or 7,000 miles depending on variant).

In summary, Fuji/Subaru states that it believes the noncompliance is inconsequential to motor vehicle safety because the expected occurrence rate for the noncompliance is less than one percent (about 0.8%); a complete absence of illumination on the telltale gives a clear indication to the vehicle

[1] On April 8, 2010, Fuji provided the actual start of production dates. The start of production for the subject Subaru Legacy passenger cars was June 1, 2009, and the start of production date for the subject Outback multipurpose passenger vehicles was June 15, 2009.

[2] The estimate of a less than one percent frequency rate for the noncompliance was based on Fuji's inspection of approximately 5,400 vehicles on July 2–10, 2009, at their Subaru Automotive Indiana plant after the noncompliance was discovered. Of this total, the Company found 45 models with the noncompliance, or about 0.8% of the inspected vehicles.

[3] Fuji's petition, which was filed under 49 CFR Part 556, requests an agency decision to exempt Fuji as importer from the notification and recall responsibilities of 49 CFR Part 573 for 3,405 vehicles manufactured prior to July 1, 2009. However, the agency cannot relieve Fuji distributors of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of any of the subject vehicles under their control after Fuji recognized that the subject noncompliance existed. Those vehicles must be brought into conformance, exported, or destroyed.

[4] The 2010 Subaru Legacy and Outback models' telltale has both an air bag suppression status indicator for ON and OFF. Thus, either ON or OFF on the telltale should be illuminated whenever the ignition is on.

owner to quickly report a problem to the Subaru dealer; the Company's vibration testing supports the conclusion that this noncompliance is not likely to later occur in vehicles that were produced without the noncompliance; and Dealers will also be instructed to check both the telltale and display at the first scheduled service (at 3,750 or 7,000 miles depending on variant) and will receive a technical service bulletin (TSB) with repair instructions for any vehicles in their inventory, which had not been inspected or repaired prior to shipment to dealers or for vehicles where the owner reports a telltale/multi-function display problem.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance.

Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. *By mail addressed to:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

b. By hand delivery to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

c. *Electronically:* by logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/*. Follow the online instructions for submitting comments. Comments may also be faxed to 1–202–493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: May 19, 2010.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at CFR 1.50 and 501.8)

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2010–8981 Filed 4–16–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control ("OFAC") is publishing the names of two individuals whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act ("Kingpin Act") (21 U.S.C. 1901–1908, 8 U.S.C. 1182).

DATES: The designation by the Director of OFAC of the two individuals identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on April 8, 2010.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

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

Background

The Kingpin Act became law on December 3, 1999. The Kingpin Act establishes a program targeting the activities of significant foreign narcotics traffickers and their organizations on a worldwide basis. It provides a statutory framework for the President to impose sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Secretary of the Treasury consults with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security when designating and blocking the property and interests in property, subject to U.S. jurisdiction, of persons who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On April 8, 2010, the Director of OFAC designated two individuals whose property and interests in property are blocked pursuant to section 805(b) of the Foreign Narcotics Kingpin Designation Act. The names of the two individuals are as follows:

1. NA TCHUTO, Jose Americo Bubo (a.k.a. NA TCHUTE, Jose Americo Bubo); DOB 12 Jun 1952; POB N'cala, Guinea-Bissau; nationality Guinea-Bissau; Former Navy Chief of Staff of Guinea-Bissau (individual) [SDNTK]

2. CAMARA, Ibraima Papa (a.k.a. CAMARA, Ibrahima Papa); nationality

Guinea-Bissau; Air Force Chief of Staff of Guinea-Bissau (individual) [SDNTK]

Dated: April 8, 2010.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2010–8915 Filed 4–16–10; 8:45 am]

BILLING CODE 4810–AL–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, "Notice Regarding Unauthorized Access to Customer Information." The OCC is also giving notice that it has submitted the collection to OMB for review.

DATES: You should submit comments by May 19, 2010.

ADDRESSES: Communications Division, Office of the Comptroller of the Currency, Mailstop 2–3, *Attention:* 1557–0227, 250 E Street, SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874–5274 or by electronic mail to *regs.comments@occ.treas.gov.* You may personally inspect and photocopy the comments at the OCC, 250 E Street, SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–4700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, you should send a copy of your comments to: OCC Desk Officer, 1557–0227, 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 or a copy of the collection 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 extend, without revision, the approval of the following information collection:

Title: Notice Regarding Unauthorized Access to Customer Information.

OMB Control No.: 1557–0227.

Description: Section 501(b) of the Gramm-Leach-Bliley Act (15 U.S.C. 6901) requires the OCC to establish standards for national banks relating to administrative, technical, and physical safeguards to: (1) Insure the security and confidentiality of customer records and information; (2) protect against any anticipated threats or hazards to the security or integrity of such records; and (3) protect against unauthorized access to, or use of, such records or information that could result in substantial harm or inconvenience to any customer.

The Interagency Guidelines Establishing Information Security Standards, 12 CFR part 30, Appendix B (Security Guidelines), implementing section 501(b), require each bank to consider and adopt a response program, if appropriate, that specifies actions to be taken when the bank suspects or detects that unauthorized individuals have gained access to customer information.

The Interagency Guidance on Response Programs for Unauthorized Customer Information and Customer Notice (Breach Notice Guidance),[1] which interprets the Security Guidelines, states that, at a minimum, a bank's response program should contain procedures for the following:

(1) Assessing the nature and scope of an incident, and identifying what customer information systems and types of customer information have been accessed or misused;

(2) Notifying its primary Federal regulator as soon as possible when the bank becomes aware of an incident involving unauthorized access to, or use of, sensitive customer information;

(3) Consistent with the OCC's Suspicious Activity Report regulations, notifying appropriate law enforcement authorities, as well as filing a timely SAR in situations in which Federal criminal violations require immediate attention, such as when a reportable violation is ongoing;

(4) Taking appropriate steps to contain and control the incident in an effort to prevent further unauthorized access to, or use of, customer information, for example, by monitoring, freezing, or closing affected accounts, while preserving records and other evidence; and

(5) Notifying customers when warranted.

This collection of information covers the notice provisions in the Breach Notice Guidance.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals; Businesses or other for-profit.

Estimated Number of Respondents: 25.

Estimated Time per Respondent:

Developing notices: 16 hours.

Notifying customers: 20 hours.

Estimated Total Annual Burden: 900 hours.

Frequency of Response: On occasion.

The OCC issued a 60-day **Federal Register** notice on February 3, 2010 (75 FR 5641). 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 OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection;

(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;

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information; and

(f) Whether the estimates need to be adjusted based upon banks' experiences regarding the number of actual security breaches that occur.

Dated: April 13, 2010.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. 2010–8828 Filed 4–16–10; 8:45 am]

BILLING CODE P

[1] 12 CFR part 30, Appendix B, Supplement A, *Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice.*

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900—New (Insurance Surveys)]

Agency Information Collection (Insurance Surveys) Activities Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before May 19, 2010.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503, (202) 395–7316. Please refer to "OMB Control No. 2900—New (Insurance Surveys)" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, FAX (202) 273–0443 or *e-mail: denise.mclamb@mail.va.gov.* Please refer to "OMB Control No. 2900—New (Insurance Surveys)."

SUPPLEMENTARY INFORMATION:

Titles: Insurance Surveys.

OMB Control Number: 2900—New (Insurance Surveys).

Type of Review: New collection.

Abstract: VBA administers integrated programs of benefits and services, established by law for veterans and their survivors, and service personnel. Executive Order 12862, Setting Customer Service Standards, requires Federal agencies and departments to identify and survey its customers to determine the kind and quality of services they want and their level of satisfaction with existing service. Customer satisfaction surveys are used to gauge customer perceptions of VA services as well as customer expectations and desires.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on February 20, 2010, at pages 6792–6793.

Affected Public: Individuals or Households.

Estimated Annual Burden: 48 hours.

Estimated Average Burden per Respondent: 6 minutes.

Frequency of Response: Monthly.

Estimated Number of Respondents: 480.

Dated: April 13, 2010.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2010–8801 Filed 4–16–10; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0092]

Agency Information Collection (Rehabilitation Needs Inventory) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before May 19, 2010.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to "OMB Control No. 2900–0092" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, FAX (202) 273–0443 or e-mail *denise.mclamb@mail.va.gov.* Please refer to "OMB Control No. 2900–0092."

SUPPLEMENTARY INFORMATION:

Title: Rehabilitation Needs Inventory (Chapter 31, Title 38 U. S. Code, VA Form 28–1902w.

OMB Control Number: 2900–0092.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 28–1902w is mailed to service-connected disabled veterans who submitted an application for vocational rehabilitation benefits. VA will use data collected to determine the types of rehabilitation program the veteran will need.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on February 10, 2010, at page 6793.

Affected Public: Individuals or households.

Estimated Annual Burden: 45,000 hours.

Estimated Average Burden per Respondent: 45 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 60,000.

Dated: April 13, 2010.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2010–8802 Filed 4–16–10; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900—New (VA Form 0857c)]

Agency Information Collection (Reasonable Accommodation) Activities Under OMB Review

AGENCY: Office of Human Resources and Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–21), this notice announces that the Office of Human Resources and Administration (OHR&A), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The

PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before *May 19, 2010.*

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to "OMB Control No. 2900—New (VA Form 0857c)" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 273–0443 or e-mail *denise.mclamb@.va.gov.* Please refer to "OMB Control No. 2900—New (VA Form 0857c)".

SUPPLEMENTARY INFORMATION:

Titles:

a. Request for Reasonable Accommodation, VA Form 0857c.

b. Authorization for Limited Release of Medical Information, VA Form 0857e.

OMB Control Number: 2900—New (VA Form 0857c).

Type of Review: Existing collection in use without an OMB control number.

Abstract: Applicants with a disability who are seeking a position at VA complete VA Form 0857c to request reasonable accommodation such as an interpreter or adaptive equipment during the application and interview process. In order to substantiate their claim for reasonable accommodation, applicants must complete VA Form 0857e to authorize their provider to release medical information to VA. The data collected will be used to determine the applicant's entitlement to reasonable accommodation.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on February 10, 2010, at page 6792.

Affected Public: Individuals or households.

Estimated Annual Burden: 18 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 35.

Dated: April 13, 2010.

By direction of the Secretary.

Denise McLamb,

Enterprise Records Service.

[FR Doc. 2010–8803 Filed 4–16–10; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

National Research Advisory Council; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that the National Research Advisory Council will hold a meeting on Tuesday, May 11, 2010, in room GL–20 at the Greenhoot Cohen Building, 1722 Eye Street NW., Washington, DC. The meeting will convene at 9:30 a.m. and end at 4 p.m. The meeting is open to the public.

The purpose of the Council is to provide external advice and review for VA's research mission. The agenda will include a review of the VA research portfolio, ethics training and a scientific presentation on basic sciences research. The Council will also provide feedback on the direction/focus of VA's research initiatives.

Time will be allocated for receiving public comments at 3:15 p.m. to 4 p.m. Public comments will be limited to five minutes each. Individuals who speak are invited to submit a 1–2 page summary of their comments at the time of the meeting for inclusion in the official meeting record.

Members of the public may direct questions or submit written statements for review by the Committee in advance of the meeting to Ms. Margaret Hannon, Designated Federal Officer, Department of Veterans Affairs, Office of Research and Development (12) 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail at *Margaret.Hannon@va.gov.* Any member of the public wishing to attend the meeting or wishing further information should contact Ms. Hannon at (202) 461–1696.

Dated: April 13, 2010.

By Direction of the Secretary:

Vivian Drake,

Acting Committee Management Officer.

[FR Doc. 2010–8823 Filed 4–16–10; 8:45 am]

BILLING CODE P

Federal Register

Monday,
April 19, 2010

Part II

Department of Health and Human Services

Food and Drug Administration

Amended Authorizations of Emergency Use of Zanamivir, Oseltamivir Phosphate, and Peramivir; Authorization of Emergency Use of Certain In Vitro Diagnostic Devices; Availability; Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0276]

Amended Authorizations of Emergency Use of Certain Antiviral Drugs Zanamivir and Oseltamivir Phosphate; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing amendments to the two Emergency Use Authorizations (EUAs) (the Authorizations) for certain products from the neuraminidase class of antivirals, zanamivir and oseltamivir phosphate, issued on April 27, 2009, under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Centers for Disease Control and Prevention (CDC). On July 14, 2009, in response to a request from CDC, FDA amended and reissued in its entirety the Authorization for certain oseltamivir phosphate products. On October 30, 2009, in response to a request from CDC, among other reasons, FDA amended and reissued in their entirety the Authorization letters for certain zanamivir and oseltamivir phosphate products. Finally, on November 4, 2009, FDA amended and reissued in its entirety the Authorization letter for certain zanamivir inhalation powder. The Authorization letter for certain oseltamivir phosphate products, as amended on October 30, 2009, and the Authorization letter for certain zanamivir inhalation powder, as amended on November 4, 2009, including explanations for their reissuance, are reprinted in this document.

DATES: The amended Authorizations are effective as of October 30, 2009.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization(s) may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: RADM Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Amendment to the April 27, 2009, Authorizations for Certain Products From the Neuraminidase Class of Antivirals, Zanamivir and Oseltamivir Phosphate

On April 26, 2009, under section 564(b)(1)(C) of the act (21 U.S.C. 360bbb-3(b)(1)(C)), the Acting Secretary of the Department of Health and Human Services (the Acting Secretary) determined that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. The determination of emergency has been renewed. On April 26, 2009, under section 564(b) of the act, and on the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals, zanamivir and oseltamivir phosphate, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). On April 26, 2009, CDC requested and, on April 27, 2009, FDA issued EUAs for zanamivir inhalation powder and certain oseltamivir phosphate capsules and oral suspension for the treatment and prophylaxis of influenza, accompanied by emergency use instructions, which are authorized under the EUAs. On April 27, 2009, FDA also amended the EUAs for zanamivir and oseltamivir phosphate, including the emergency use instructions authorized under the EUAs. On August 4, 2009, notice of the determination and declaration was published in the **Federal Register** (74 FR 38628, August 4, 2009), as was the notice of the April 27, 2009, Authorizations (74 FR 38648, August 4, 2009).

On July 7, 2009, CDC submitted a request to amend the Authorization for certain oseltamivir phosphate products to address, among other things, issues relating to certain oseltamivir phosphate oral suspension products that had passed testing under the Federal Government's Shelf Life Extension Program for use beyond their expiration dates. In response to CDC's request, on July 14, 2009, FDA amended the Authorization letter and reissued the Authorization letter in its entirety. Because the subsequent October 30, 2009, amendment to the Authorization for certain oseltamivir phosphate products incorporated the July 2009 amendment in its entirety, the July 2009 amendment to the Authorization letter for certain oseltamivir phosphate products is not reprinted in this document.

On October 29, 2009, CDC submitted another request to amend both of the Authorizations for certain zanamivir and oseltamivir phosphate products to address, among other things, issues relating to certain zanamivir inhalation powder and oseltamivir phosphate capsules deployed from the Strategic National Stockpile (SNS) that were beyond or would be beyond their expiration date before the declaration of emergency underlying the EUA terminated. FDA also became aware of other zanamivir inhalation powder and oseltamivir phosphate capsules in addition to those held in or deployed from the SNS that were beyond or would be beyond their expiration date before the declaration of emergency underlying the EUA terminated. FDA amended both of the Authorization letters to address both of these categories products. Among the other reasons that FDA amended the Authorization for certain oseltamivir phosphate products was to update the information for health care providers to include dosing recommendations based on weight for children younger than 1 year of age. Therefore, in response to CDC's October 2009 request, among other reasons, FDA amended and reissued both of the Authorization letters in their entirety on October 30, 2009. Finally, on November 4, 2009, to include a condition of Authorization inadvertently omitted, FDA again amended the Authorization letter for certain zanamivir inhalation powder.

II. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the Internet at *http://www.regulations.gov.*

III. The Authorizations

Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the act were met, on April 27, 2009, FDA authorized the emergency use of certain zanamivir inhalation powder and certain oseltamivir phosphate capsules and oral suspension for the treatment and prophylaxis of influenza, accompanied by emergency use information, subject to the terms and conditions of the authorizations.

The Authorization (as amended on October 30, 2009) for certain oseltamivir phosphate capsules and oral suspension follows and provides an explanation of

the reasons for its issuance, as required by section 564(h)(1) of the act:

October 30, 2009

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D–14
Atlanta, GA 30333

Dear Dr. Frieden:

On April 27, 2009, a letter was issued authorizing the emergency use of certain oseltamivir phosphate capsules and oral suspension for treatment and prophylaxis of influenza subject to the terms of that letter. On the same day, an amendment to the letter was also issued.[1] On July 14, 2009, an amendment to the letter was issued addressing certain oseltamivir phosphate products identified by FDA that have passed testing under the federal government's Shelf Life Extension Program (SLEP). I am issuing this letter in response to your October 29, 2009 request to address, among other things, issues that have arisen relating to certain oseltamivir phosphate capsules deployed from the Strategic National Stockpile (SNS) that are beyond or will be beyond their expiration date before the declaration of emergency underlying this EUA has terminated. FDA has also become aware of certain oseltamivir phosphate capsules in addition to those held in or deployed from the Strategic National Stockpile that are beyond or will be beyond their expiration date before the declaration of emergency underlying the EUA has terminated. FDA is issuing this amendment to address both of these categories of oseltamivir phosphate capsules, as further described below. The letter of authorization, as amended, appears below in its entirety:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of certain oseltamivir phosphate capsules and oral suspension for treatment and prophylaxis of influenza, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (DHHS) determined that a public health emergency exists involving Swine Influenza A (now called 2009-H1N1 flu) that affects or has significant potential to affect national security. Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of DHHS then declared an emergency justifying the authorization of the emergency use of certain oseltamivir phosphate products subject to the terms of any authorization issued under section 564(a) of the Act (21 U.S.C. § 360bbb-3(a)). The Secretary's determination of emergency has been renewed. The Secretary's April 26, 2009 declaration of emergency justifying an EUA remains in effect.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(b)) are met, I am authorizing the emergency use of certain oseltamivir phosphate products[2] for the treatment and prophylaxis of influenza, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of certain oseltamivir phosphate products for the treatment and prophylaxis of influenza meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) 2009-H1N1 flu can cause influenza, a serious or life-threatening disease or condition;

(2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that certain oseltamivir phosphate products may be effective for the treatment and prophylaxis of influenza, and that the known and potential benefits of certain oseltamivir phosphate products, when used for the treatment and prophylaxis of influenza, outweigh the known and potential risks of such products; and

(3) There is no adequate, approved, and available alternative to the emergency use of certain oseltamivir phosphate products for the treatment and prophylaxis of influenza.[3]

Therefore, I have concluded that the emergency use of certain oseltamivir phosphate products for the treatment and prophylaxis of influenza meets the above statutory criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of authorized oseltamivir phosphate products for the treatment and prophylaxis of influenza for individuals exposed to 2009-H1N1 flu. The emergency use of authorized oseltamivir phosphate products under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

The authorized oseltamivir phosphate products are as follows:

- Tamiflu (oseltamivir phosphate) (30 mg, 45 mg, and 75 mg) capsules
- Tamiflu (oseltamivir phosphate) oral suspension

Oseltamivir phosphate products are approved and indicated for the treatment of uncomplicated acute illness due to influenza infections in patients 1 year and older who have been symptomatic for no more than 2 days. Oseltamivir phosphate products are also approved and indicated for the prophylaxis of influenza in patients 1 year and older.[4]

1. The above oseltamivir phosphate products are authorized for use in patients less than 1 year old. Such products are also authorized for use at later time points (i.e., patients who are symptomatic for more than 2 days) and/or in patients sick enough to require hospitalization (i.e., patients who do not have "uncomplicated acute illness" per se).

2. The above oseltamivir phosphate products labeled consistent with the manufacturer's label are authorized to be distributed under this EUA. Such products are authorized to be distributed or dispensed without the requisite prescription label information under section 503(b)(2) of the Act (e.g., name and address of dispenser, serial number, date of prescription or of its filling, name of prescriber, name of patient, if stated on prescription, directions for use and cautionary statements, if contained in the prescription), except for product described in paragraph 3c. below that is held by entities that are not public health authorities.

3a. The above oseltamivir phosphate products may include products that are deployed from the SNS and that have passed testing under the federal government's Shelf Life Extension Program (SLEP) for use beyond their expiration dates.

3b. Certain oseltamivir phosphate products that are: (i) identified by FDA, (ii) deployed from the SNS, and (iii) have passed SLEP testing are authorized to be distributed or dispensed without information on the label about the use of the products beyond their expiration dates. The appropriate public health authorities are authorized to label these products with information about the use of the products beyond their expiration dates should the appropriate public health authorities choose to do so.

3c. Certain oseltamivir phosphate capsules that are (i) identified by FDA and (ii) are beyond or will be beyond their expiration dates before the declaration of emergency underlying this EUA has terminated are authorized to be distributed or dispensed subject to the terms and conditions of this authorization.

4. The above oseltamivir phosphate products are authorized to be accompanied by the following written information pertaining to the emergency use, which are authorized to be made available to health care providers[5] and recipients:

- Fact Sheet for Health Care Provider
- Fact Sheet for Patients and Parents/Caretakers

CDC and the appropriate public health authorities are also authorized to make available additional information relating to the emergency use of authorized oseltamivir phosphate products that is consistent with, and does not exceed, the terms of this letter of authorization. (See section IV).

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized oseltamivir phosphate products, when used for the treatment and prophylaxis of influenza, outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized oseltamivir phosphate products may be effective for the treatment and prophylaxis of influenza pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available, including the information supporting the conclusions described in Section I above, and concludes that the authorized oseltamivir phosphate products, when used for the treatment and prophylaxis of influenza in the specified population, meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.[6]

Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHHS's determination under section 564(b)(1)(C) described above and the Secretary of DHHS's corresponding declaration under section 564(b)(1), the oseltamivir phosphate products described above are authorized for the treatment and prophylaxis of influenza for individuals exposed to 2009-H1N1 flu.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Current Good Manufacturing Practice

In the letter dated April 27, 2009, current good manufacturing practice (CGMP) requirements were waived with respect to the holding of authorized oseltamivir phosphate products by CDC and other public health authorities for a period of ninety days (the "First Waiver"). As of the date of the July 14, 2009 letter, I terminated the First Waiver and replaced it with the following waiver, which remains in effect:

Although authorized oseltamivir phosphate products should be held in accordance with CGMP holding requirements, including appropriate product storage conditions[7], I am waiving CGMP requirements with respect to the holding of authorized oseltamivir phosphate products by CDC and other public health authorities for a maximum of 90 days (consecutive or non-consecutive) from the date of shipment to the public health authority. However, this waiver is also limited in that the products may be stored with temperature excursions in excess of 40°C for a total cumulative period of 14 days (consecutive or non-consecutive) within that 90 days. Other temperature excursions outside labeled temperature storage conditions and not in excess of 40°C are permitted within the 90-day period.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

A. CDC will verify that oseltamivir phosphate products distributed to the Receive, Stage, Storage (RSS) sites:
(i) are within unexpired labeled dates,
(ii) have passed SLEP testing, whether relabeled or not, and are within the dates supported by SLEP testing, or
(iii) are beyond or will be beyond their expiration dates before the termination of the Secretary's declaration of emergency and have been identified by FDA under Section II.3.c.

B. For oseltamivir phosphate products identified in Section II.3.b. and c. of this letter, information on the lot numbers of the oseltamivir phosphate products identified by FDA will be made available by CDC to the appropriate public health authorities, healthcare providers, and recipients (patients and parents) through appropriate means.

C. CDC will ensure that the appropriate public health authorities are informed of this EUA, including the terms and conditions herein.

D. CDC will make available to the appropriate public health authorities through appropriate means the authorized Fact Sheet for Health Care Providers, Fact Sheet for Patients and Parents/Caretakers, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized oseltamivir phosphate products.

E. Only CDC may request changes to the authorized Fact Sheet for Health Care Providers and authorized Fact Sheet for Patients and Parents/Caretakers. Such requests will be made by contacting FDA concerning FDA review and approval.

Public Health Authorities[8]

F. The appropriate public health authorities will ensure that authorized oseltamivir phosphate products are distributed to recipients in accordance with applicable laws and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency.[9] However, the appropriate public health authorities will ensure that authorized oseltamivir phosphate products are distributed, dispensed, and/or administered to patients less than 1 year old only under the supervision of a licensed healthcare provider.

G. The appropriate public health authorities will make available through appropriate means authorized Fact Sheet for Health Care Providers, Fact Sheet for Patients and Parents/Caretakers, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized oseltamivir phosphate products.

H. The appropriate public health authorities are authorized to label the oseltamivir phosphate products identified in Section II.3.b. with information about the use of the products beyond their expiration dates, should the appropriate public health authorities choose to do so.

Entities That Are Not Public Health Authorities

I. Entities acting under Section II.3.c. that are neither (a) public health authorities nor (b) acting in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures will ensure that authorized oseltamivir phosphate capsules are prescribed and dispensed to recipients in accordance with applicable laws that are consistent with this letter of authorization and with applicable federal public health guidelines that are consistent with this letter of authorization.

J. Entities acting under Section II.3.c. that are neither (a) public health authorities nor (b) acting in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and that dispense authorized oseltamivir phosphate products, will make available through appropriate means the authorized Fact Sheet for Health Care Providers, Fact Sheet for Patients and Parents, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized oseltamivir phosphate capsules.

K. Entities acting under Section II.3.c. that are neither (a) public health authorities nor (b) acting in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and that dispense authorized oseltamivir phosphate products, will verify that the oseltamivir phosphate products that are beyond or will be beyond their expiration dates before the termination of the Secretary's declaration of emergency have been identified by FDA under Section II.3.c.

CDC and Public Health Authorities

L. CDC and the appropriate public health authorities are also authorized to make available additional information relating to the emergency use of authorized oseltamivir phosphate products that is consistent with, and does not exceed, the terms of this letter of authorization.

The emergency use of authorized oseltamivir phosphate products as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Specifically, the letter was amended in the following two respects: (1) the reference on page 3 to "Fact Sheet for Patients and Recipients" was revised to read "Fact Sheet for Patients and Parents"; and (2) the correct authorized versions of the Tamiflu Fact Sheet for Health Care Providers and Tamiflu Fact Sheet for Patients and Parents were attached to the letter.

[2] FDA is authorizing the emergency use of Tamiflu (oseltamivir phosphate) (30 mg, 45 mg, and 75 mg) capsules and oral suspension for treatment and prophylaxis of influenza as described in the scope section of this letter (Section II). For ease of reference, this letter of authorization will use the terms "certain oseltamivir phosphate product(s)" and "authorized oseltamivir phosphate product(s)."

[3] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

[4] The approved labeling also states the following: "The following points should be considered before initiating treatment or prophylaxis with [oseltamivir phosphate products]: [Oseltamivir phosphate products are] not a substitute for early vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use [oseltamivir phosphate products.]"

[5] It is possible that public health officials or other volunteers might distribute authorized oseltamivir phosphate products to recipients (except as limited in IV.F below) , if permitted, in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency. For ease of reference, this letter will use the term "health care provider(s)" to refer collectively to these individuals.

[6] Please note that with respect to authorized oseltamivir phosphate products for use in patients less than 1 year old, the conclusions above are based on limited data available for review under the limited timeframe given the circumstances of the emergency. The conclusions above may evolve as the emergency circumstances evolve and as more information becomes available.

[7] See Tamiflu Capsule and Oral Suspension product labeling or http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021087s047,%20021246s033lbl.pdf for oseltamivir phosphate product storage conditions.

[8] Conditions F, G, and H apply to entities that are not public health authorities, but are acting under the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures.

[9] For more information about the terms "Authority Having Jurisdiction" and "covered countermeasures," see Public Readiness and Emergency Preparedness (PREP) Act, sections 319F-3 and 319F-4 of the Public Health Service Act (codified at 42 U.S.C. §§ 247d-6d, 247d-6e), and the PREP Act declaration regarding pandemic influenza antivirals. See http://www.hhs.gov/disasters/discussion/planners/prepact/.

The Authorization (as amended on November 4, 2009) for certain zanamivir inhalation powder follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

November 4, 2009

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D–14
Atlanta, GA 30333

Dear Dr. Frieden:

On April 27, 2009, a letter was issued authorizing the emergency use of certain zanamivir inhalation powder for treatment and prophylaxis of influenza subject to the terms of that letter. On the same day, an amendment to the letter was also issued.[1] On October 30, 2009, the Food and Drug Administration (FDA) issued an amendment to the April letter in response to your October 29, 2009 request to address, among other things, issues that have arisen relating to certain zanamivir products deployed from the Strategic National Stockpile (SNS) that are beyond or will be beyond their expiration date before the declaration of emergency underlying this Emergency Use Authorization (EUA) has terminated. FDA had also become aware of certain zanamivir products in addition to those held in or deployed from the SNS that are beyond or will be beyond their expiration date before the declaration of emergency underlying the EUA has terminated. FDA issued the October 30, 2009 amendment to address both categories of zanamivir products, as further described below. I hereby amend the October 30 letter to include condition J below and to make other minor corrections. The letter of authorization, as amended, is being reissued in its entirety with the amendments incorporated.

This letter is in response to your request that FDA issue an EUA for the emergency use of zanamivir inhalation powder for treatment and prophylaxis of influenza, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (DHHS) determined that a public health emergency exists involving Swine Influenza A (now called 2009-H1N1 flu) that affects or has significant potential to affect national security. Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of DHHS then declared an emergency justifying the authorization of the emergency use of certain zanamivir products subject to the terms of any authorization issued under section 564(a) of the Act (21 U.S.C. § 360bbb-3(a)). The Secretary's determination of emergency has been renewed. The Secretary's April 26, 2009 declaration of emergency justifying an EUA remains in effect.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(b)) are met, I am authorizing the emergency use of certain zanamivir products[2] for the treatment and prophylaxis of influenza, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of certain zanamivir products for the treatment and prophylaxis of influenza meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) 2009-H1N1 flu can cause influenza, a serious or life-threatening disease or condition;

(2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that certain zanamivir products may be effective for the treatment and prophylaxis of influenza, and that the known and potential benefits of certain zanamivir products, when used for the treatment and prophylaxis of influenza, outweigh the known and potential risks of such products; and

(3) There is no adequate, approved, and available alternative to the emergency use of certain zanamivir products for the treatment and prophylaxis of influenza.[3]

Therefore, I have concluded that the emergency use of certain zanamivir products for the treatment and prophylaxis of influenza meets the above statutory criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of authorized zanamivir products for the treatment and prophylaxis of influenza for individuals exposed to 2009-H1N1 flu. The emergency use of authorized zanamivir products under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

The authorized zanamivir products are as follows:

- Relenza (zanamivir) Inhalation Powder

Zanamivir products are approved and indicated for the treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients 7 years of age and older who have been symptomatic for no more than 2 days. Zanamivir products are also approved and indicated for prophylaxis of influenza in adults and pediatric patients 5 years of age and older.[4]

1. The above zanamivir products are authorized for use at later time points (i.e., patients who are symptomatic for more than 2 days) and/or in patients sick enough to require hospitalization (i.e., patients who do not have "uncomplicated acute illness" per se).

2. The above zanamivir products labeled consistent with the manufacturer's label are authorized to be distributed under this EUA. Such products are authorized to be distributed or dispensed without the requisite prescription label information under section 503(b)(2) of the Act (e.g., name and address of dispenser, serial number, date of prescription or of its filling, name of prescriber, name of patient, if stated on prescription, directions for use and cautionary statements, if contained in the prescription), except for product described in paragraph 3 below that is held by entities that are not public health authorities.

3. Certain zanamivir products that are (i) identified by FDA and (ii) are beyond or will be beyond their expiration dates before the declaration of emergency underlying this EUA has terminated are authorized to be distributed or dispensed subject to the terms and conditions of this authorization.

4. The above zanamivir products are authorized to be accompanied by the following written information pertaining to the emergency use, which are authorized to be made available to health care providers[5] and recipients:

- Fact Sheet for Health Care Provider
- Fact Sheet for Patients and Parents/Caregivers

CDC and the appropriate public health authorities are also authorized to make available additional information relating to the emergency use of authorized zanamivir products that is consistent with, and does not exceed, the terms of this letter of authorization. (See section IV).

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized zanamivir products, when used for the treatment and prophylaxis of influenza, outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized zanamivir products may be effective for the treatment and prophylaxis of influenza pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available, including the information supporting the conclusions described in Section I above, and concludes that the authorized zanamivir products, when used for the treatment and prophylaxis of influenza in the specified population, meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHHS's determination under section 564(b)(1)(C) described above and the Secretary of DHHS's corresponding declaration under section 564(b)(1), the zanamivir products described above are authorized for the treatment and prophylaxis of influenza for individuals exposed to 2009-H1N1 flu.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Current Good Manufacturing Practice

In the letter dated April 27, 2009, current good manufacturing practice (CGMP) requirements were waived with respect to the holding of authorized zanamivir products by CDC and other public health authorities for a period of ninety days (the "First Waiver"). As of the date of this letter, I terminate the First Waiver and replace it with the following waiver:

Although authorized zanamivir products should be held in accordance with CGMP holding requirements, including appropriate product storage conditions,[6] I am waiving CGMP requirements with respect to the monitoring and calculating of mean kinetic temperature by CDC and other public health authorities so long as, to the extent practicable given the circumstances of the emergency, temperature is monitored. I also am waiving CGMP requirements with respect to holding at the labeled storage conditions in that the products may be stored with temperature excursions up to 40°C for a total cumulative period of 7 days (consecutive or non-consecutive) from the date of shipment to the public health authority.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

A. CDC will verify that zanamivir products distributed to the Receive, Stage, Storage (RSS) sites are within their labeled expiration dates, or are beyond or will be beyond their expiration dates before the termination of the Secretary's declaration of emergency and have been identified by FDA under Section II.3.

B. For zanamivir products identified in Section II.3 of this letter, information on the lot numbers of the zanamivir products identified by FDA will be made available by CDC to the appropriate public health authorities, healthcare providers, and recipients (patients and parents/caregivers) through appropriate means.

C. CDC will ensure that the appropriate public health authorities are informed of this EUA, including the terms and conditions herein.

D. CDC will make available to the appropriate public health authorities through appropriate means the authorized Fact Sheet for Health Care Providers, authorized Fact Sheet for Patients and Parents/Caregivers, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized zanamivir products.

E. Only CDC may request changes to the authorized Fact Sheet for Health Care Providers and authorized Fact Sheet for Patients and Parents/Caregivers. Such requests will be made by contacting FDA concerning FDA review and approval.

Public Health Authorities[7]

F. The appropriate public health authorities will ensure that authorized zanamivir products are distributed to recipients in accordance with applicable laws and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency.[8]

G. The appropriate public health authorities will make available through appropriate means authorized Fact Sheets for Health Care Providers, authorized Fact Sheets for Patients and Parents/Caregivers, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized zanamivir products.

Entities That Are Not Public Health Authorities

H. Entities acting under Section II.3 that are neither (a) public health authorities nor (b) acting in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense covered countermeasures will ensure that authorized zanamivir products are prescribed and dispensed to recipients in accordance with applicable laws that are consistent with this letter of authorization and with applicable federal public health guidelines that are consistent with this letter of authorization.

I. Entities acting under Section II.3 that are neither (a) public health authorities nor (b) acting in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and that dispense authorized zanamivir products, will make available through appropriate means the authorized Fact Sheet for Health Care Providers, Fact Sheet for Patients and Parents/Caregivers, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized zanamivir products.

J. Entities acting under Section II.3 that are neither (a) public health authorities nor (b) acting in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and that dispense authorized zanamivir products, will verify that the zanamivir products that are beyond or will be beyond their expiration dates before the termination of the Secretary's declaration of emergency have been identified by FDA under Section II.3.

CDC and Public Health Authorities

K. CDC and the appropriate public health authorities are also authorized to make available additional information relating to the emergency use of authorized zanamivir products that is consistent with, and does not exceed, the terms of this letter of authorization.

The emergency use of authorized zanamivir products as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Specifically, the letter was amended in the following respect: the correct authorized versions of the Zanamivir Fact Sheet for Health Care Providers and Zanamivir Summary Fact Sheet for Patients and Parents were attached to the letter.

[2] FDA is authorizing the emergency use of Relenza (zanamivir) inhalation powder for treatment and prophylaxis of influenza as described in the scope section of this letter (Section II). For ease of reference, this letter of authorization will use the terms "certain zanamivir product(s)" and "authorized zanamivir product(s)."

[3] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

[4] Zanamivir products are not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease) due to risk of serious bronchospasm. Zanamivir products have not been proven effective for treatment of influenza in individuals with underlying airways disease. Zanamivir products have not been proven effective for prophylaxis of influenza in the nursing home setting. Zanamivir products are not a substitute for early vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use zanamivir products. There is no evidence for efficacy of zanamivir in any illness caused by agents other than Influenza A and B. Patients should be advised that the use of zanamivir products for treatment of influenza has not been shown to reduce the risk of transmission of influenza to others.

[5] It is possible that public health officials or other volunteers might distribute authorized zanamivir products to recipients, if permitted, in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency. For ease of reference, this letter will use the term "health care provider(s)" to refer collectively to these individuals.

[6] See FDA-approved product labeling for zanamivir products storage conditions (http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021036s017lbl.pdf)

[7] Conditions F and G apply to entities that are not public health authorities, but are acting under the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures.

[8] For more information about the terms "Authority Having Jurisdiction" and "covered countermeasures," see Public Readiness and Emergency Preparedness (PREP) Act, sections 319F-3 and 319F-4 of the Public Health Service Act (codified at 42 U.S.C. §§ 247d-6d, 247d-6e), and the PREP Act declaration regarding pandemic influenza antivirals. See http://www.hhs.gov/disasters/discussion/planners/prepact/.

Dated: April 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8603 Filed 4–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0521]

Amended Authorization of Emergency Use of the Antiviral Product Peramivir Accompanied by Emergency Use Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the Emergency Use Authorization (EUA) (the Authorization) for peramivir injection 200 milligrams (mg)/20 milliliter (mL) (10 mg/mL) single use vial manufactured for BioCryst Pharmaceuticals, Inc. (BioCryst) for intravenous (IV) administration in certain adult and pediatric patients issued on October 23, 2009, under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Centers for Disease Control and Prevention (CDC). FDA received inquiries related to the recommended dosing for patients with renal impairment. On November 19, 2009, FDA amended the Authorization letter and reissued the Authorization letter in its entirety to provide additional clarification. The Authorization letter, as amended and reissued, which includes explanations for its reissuance, is reprinted in this notice.

DATES: The amended Authorization is effective as of November 19, 2009.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: RADM Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Amendment to the October 23, 2009, Authorization for Peramivir IV

On April 26, 2009, under section 564(b)(1)(C) of the act (21 U.S.C. 360bbb–3(b)(1)(C)), the Acting Secretary of Health and Human Services determined that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A, or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. The determination of emergency has been renewed. On October 20, 2009, under section 564(b) of the act, and on the basis of such determination, the Secretary declared an emergency justifying the authorization of the emergency use of the antiviral peramivir, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). On October 23, 2009, in response to a request from CDC, FDA issued an EUA for the emergency use of the unapproved drug peramivir administered intravenously. On November 2, 2009, notice of the determination and declaration was published in the **Federal Register** (74 FR 56640, November 2, 2009), as was the notice of the Authorization (74 FR 56644, November 2, 2009). In response to inquiries about dosing of Peramivir IV in certain patients with severe renal impairment, including those who require continuous renal replacement therapy or hemodialysis, on November 19, 2009, FDA amended the Authorization letter to amend the Fact Sheet for Health Care Providers to provide additional clarification regarding the dosing recommendations for IV peramivir and reissued the Authorization letter in its entirety. The amended dosing recommendations are provided in the amended authorized version of the Fact Sheet for Health Care Providers.

II. Electronic Access

An electronic version of this notice and the full text of the Authorization are available on the Internet at *http://www.regulations.gov.*

III. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the act were met, on October 23, 2009, FDA authorized the emergency use of the unapproved drug peramivir administered intravenously for treatment of 2009 H1N1 influenza virus in certain adult and pediatric patients. The letter of Authorization in its entirety (not including the amended authorized version of the Fact Sheet for Health Care Providers), as amended on November 19, 2009, follows:

Thomas R. Frieden, MD, MPH
Director, Centers for Disease Control and Prevention
1600 Clifton Rd, MS D–14
Atlanta, GA 30333

Dear Dr. Frieden:

On October 23, 2009, a letter was issued authorizing the emergency use of the unapproved drug peramivir in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of peramivir administered intravenously for treatment of 2009 H1N1 influenza virus (hereafter "2009 H1N1") in certain adult and pediatric patients, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb–3). FDA has received inquiries related to the recommended dosing for patients with renal impairment. The purpose of this letter is to amend the Fact Sheet for Health Care Providers to provide additional clarification regarding the dosing recommendations for IV peramivir in patients with severe renal impairment, including those who require continuous renal replacement therapy or hemodialysis. The amended authorized version of the Fact Sheet for Health Care Providers is enclosed with this letter. In addition, this version of the letter includes minor editorial changes. The letter of authorization, as amended, appears below in its entirety:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the unapproved drug peramivir administered intravenously for treatment of 2009 H1N1 influenza virus (hereafter "2009 H1N1") in certain adult and pediatric patients, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb–3).

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb–3(b)(1)(C)), the then Acting Secretary of the Department of Health and Human Services (HHS) determined that a public health emergency exists involving Swine Influenza A (now referred to as "2009 H1N1") that affects or has significant potential to affect national security. The Secretary has renewed the determination. Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb–3(b)), and on the basis of such determination, the Secretary of HHS declared an emergency justifying the authorization of the emergency use of the antiviral peramivir, accompanied by emergency use information, subject to the terms of any authorization issued under section 564(a) of the Act (21 U.S.C. § 360bbb–3(a)).

Having consulted with the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), and having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb–3(b)) are met, I am authorizing the emergency use of peramivir[1] administered intravenously for treatment of 2009 H1N1 in certain adult and pediatric patients, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of peramivir administered intravenously for treatment of 2009 H1N1 in certain adult and pediatric patients meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) 2009 H1N1 can cause influenza, a serious or life-threatening disease or condition;

(2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that peramivir may be effective when administered intravenously for the treatment of 2009 H1N1 in certain adult and pediatric patients, and that the known and potential benefits of peramivir, when administered intravenously for the treatment of 2009 H1N1 in certain adult and pediatric patients, outweigh the known and potential risks of peramivir; and

(3) there is no adequate, approved, and available alternative to the emergency use of peramivir administered intravenously for the treatment of 2009 H1N1 in certain adult and pediatric patients.[2]

Therefore, I have concluded that the emergency use of peramivir administered intravenously for the treatment of 2009 H1N1 in certain adult and pediatric patients meets the above statutory criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the emergency use of authorized peramivir for the treatment of 2009 H1N1 in certain adult and pediatric patients. The emergency use of authorized peramivir under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

Peramivir (a neuraminidase inhibitor) is an unapproved drug that it is currently being studied in clinical investigations. Peramivir is not currently approved by FDA for any use in the United States.

The authorized peramivir is as follows:

- Peramivir injection: 200mg/20mL (10 mg/mL) single use vial manufactured for BioCryst Pharmaceuticals, Inc. (BioCryst). (See Section IV.D.3. of this letter).

1. The above peramivir product is authorized only for intravenous (IV) administration.

2. The above peramivir product is authorized for the treatment of certain patients with suspected or laboratory confirmed 2009 H1N1 infection or infection due to nonsubtypable influenza A virus suspected to be 2009 H1N1 based on community epidemiology. Specifically, the peramivir product is authorized only for the following patients who are admitted to a hospital and under the care or consultation of a licensed clinician (skilled in the diagnosis and management of patients with potentially life-threatening illness and the ability to recognize and manage medication-related adverse events):

a. Adult patients for whom therapy with an IV agent is clinically appropriate, based upon one or more of the following reasons:
(i) patient not responding to either oral or inhaled antiviral therapy, or

(ii) drug delivery by a route other than IV (e.g., enteral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible, or
(iii) the clinician judges IV therapy is appropriate due to other circumstances.

b. Pediatric patients for whom an IV agent is clinically appropriate because:
(i) patient not responding to either oral or inhaled antiviral therapy, or
(ii) drug delivery by a route other than IV (e.g., enteral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible.

3. The above peramivir product may only include product distributed from Strategic National Stockpile (SNS), in which case such product is authorized only to be labeled with the enclosed label.

4. The above peramivir product is authorized to be accompanied by the following written information pertaining to the emergency use, which is enclosed and authorized to be made available to health care providers and patients (and parents/caregivers):

- Fact Sheet for Health Care Providers
- Fact Sheet for Patients and Parents/Caregivers

CDC, hospitals, and health care providers receiving authorized peramivir are also authorized to make available additional written information relating to the emergency use of authorized peramivir that is consistent with and does not exceed the terms of this letter of authorization (including the above referenced facts sheets).

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized peramivir, when used for the treatment of H1N1 in certain adult and pediatric patients, outweigh the known and potential risks of such product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized peramivir may be effective for the treatment of 2009 H1N1 in certain adult and pediatric patients pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available, including the information supporting the conclusions described in Section I of this letter above, and concludes that the authorized peramivir when used for the treatment of 2009 H1N1 in certain adult and pediatric patients, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the peramivir described above is authorized for the treatment of 2009 H1N1 in certain adult and pediatric patients.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Current Good Manufacturing Practice

This letter covers authorized peramivir as previously manufactured for BioCryst as of the date of this letter as well as authorized peramivir that may be manufactured for BioCryst after such date, insofar as FDA has determined that the methods used in, and the facilities and controls used for, the manufacturing, processing and packing of authorized peramivir are adequate to preserve its identity, strength, quality and purity.

Authorized peramivir should be held in accordance with its labeled and appropriate product storage conditions (ambient temperature, 15°C–30°C or 59°F–86°F). However, in order to ensure the delivery and availability of authorized peramivir, I am waiving current good manufacturing practice (CGMP) requirements with respect to proper storage conditions of temperature during the shipment and holding of authorized peramivir by CDC and/or its designees for a maximum of 90 days (consecutive or non-consecutive) from the date of shipment to CDC and/or its designees. Significant excursions from labeled storage conditions should be documented to the extent practicable given the circumstances of the emergency, and need not be supported by additional testing by CDC or its designees.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

A. CDC

A.1. CDC will decide how authorized peramivir will be distributed under its direction to Hospitals upon request by licensed treating clinicians at the Hospitals to the extent such decisions are consistent with and do not exceed the terms of this letter; except that CDC will ensure that authorized peramivir will be distributed to Hospitals as soon as possible within 24 hours of CDC's decision to distribute such product, to the extent practicable given the circumstances of the emergency.

A.2. CDC will maintain adequate records regarding distribution under its direction of authorized peramivir (i.e., lot numbers, quantity, receiving site, receipt date, unique identifier(s) (e.g., Peramivir Request number(s))).

A.3. CDC will notify FDA on a weekly basis (unless otherwise specified by FDA) of the quantity of and to which Hospitals authorized peramivir is distributed under its direction. CDC will also include in the notification the unique identifier(s) (e.g., Peramivir Request number(s)).

A.4. CDC will ensure that authorized peramivir is distributed for use under its direction only within the expiry dates identified by FDA. CDC will inform Hospitals receiving authorized peramivir under its direction of the expiry dates by which authorized peramivir is to be used if authorized peramivir is nearing expiry. CDC will maintain adequate records regarding the expiry dates by which authorized peramivir is to be used.

A.5. CDC will ensure that Hospitals receiving authorized peramivir under its direction are informed of this letter, including the terms and conditions as well as any authorized amendments thereto.

A.6. CDC will make available through appropriate means to the Hospitals receiving authorized peramivir under its direction the authorized Fact Sheet for Health Care Providers and Fact Sheet for Patients and Parents/Caregivers as well as any authorized amendments thereto.

A.7. CDC will perform adverse event monitoring and compliance activities (e.g., follow-up surveys) designed: (1) to ensure that selected adverse events and all medication errors associated with the use of authorized peramivir are reported to FDA as follows: the MedWatch FDA Form 3500 must be completed either online at *www.fda.gov/medwatch/report.htm* or by using a postage-paid FDA Form 3500 (available at *http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf*) and returning by fax (1-800-FDA-0178) or by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787). If there is no online internet access such reports must be made by calling 1-800-FDA-1088; (2) to ensure that such reports include in the description section of the MedWatch Form 3500 the words "Peramivir EUA" and include unique identifier(s) (e.g., Peramivir Request number(s)), and (3) to ensure that such reports are made within seven calendar days from the onset of the event. CDC will report such information to FDA upon request.

A.8. CDC will only make available additional written information relating to the emergency use of authorized peramivir to the extent that it is consistent with and does not exceed the terms of this letter (including the facts sheets referenced in Section II of this letter).

A.9. CDC will make available to FDA upon request any records maintained in connection with this letter.

B. Hospitals to Which Authorized Peramivir is Distributed

B.1 Such Hospitals will make available through appropriate means to relevant health care providers this letter, including the terms and conditions as well as any authorized amendments thereto.

B.2. Such Hospitals will make available through appropriate means to relevant health care providers and patients and/or parents/caregivers the authorized Fact Sheet for Health Care Providers and Fact Sheet for Patients and Parents/Caregivers as well as any authorized amendments thereto.

B.3. Such Hospitals will ensure that relevant health care providers abide by the institutional procedures regarding drug accountability. Such Hospitals will maintain adequate records showing receipt, use, and disposition of authorized peramivir.

B.4. Such Hospitals will ensure that the emergency use of authorized peramivir is limited to patients who are under the care or consultation of a licensed clinician (e.g., skilled in the diagnosis and management of patients with systemic illness, including recognition and management of medication-related adverse events).

B.5. Such Hospitals will conduct any follow-up requested by FDA and/or CDC regarding medication errors and adverse events.

B.6. Such Hospitals will only make available additional written information relating to the emergency use of authorized peramivir to the extent that it is consistent with and does not exceed the terms of this letter of authorization (including the facts sheets referenced in Section II of this letter).

B.7. Such Hospitals will make available to FDA and/or CDC upon request any records maintained in connection with this letter. Upon request, such Hospitals will report to FDA and/or CDC information with respect to the emergency use of authorized peramivir.

C. Health Care Providers Conducting Activities With Respect to Authorized Peramivir[3]

C.1. Health Care Providers will be aware of this letter, including the terms and conditions as well as any authorized amendments thereto. Health Care Providers will read the Fact Sheet for Health Care Providers, including the sections on Mandatory Requirements for Peramivir Administration Under Emergency Use Authorization and Considerations Prior to Peramivir Use Under EUA as well as any amendments thereto. (See Fact Sheet for Health Care Providers).

C.2. Health Care Providers prescribing and/or administering authorized peramivir will ensure that the authorized Fact Sheet for Patients and Parents/Caregivers, as well as any authorized amendments thereto, have been made available to patients and/or parents/caregivers through appropriate means. Such Health Care Providers (to the extent practicable given the circumstances of the emergency) will document in the patient's medical record that: (a) patients/caregivers have been given the Fact Sheet for Patients and Parents/Caregivers, (b) patients/caregivers have been informed of the alternatives to receiving authorized peramivir, and (c) patients/caregivers have been informed that peramivir is an unapproved drug that is authorized for use under Emergency Use Authorization.

C.3. Prescribing Health Care Providers (or their designees) will ensure that: (1) selected adverse events and all medication errors associated with the use of authorized peramivir are reported as follows: the MedWatch FDA Form 3500 must be completed either online at *www.fda.gov/medwatch/report.htm* or by using a postage-paid FDA Form 3500 (available at *http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf*) and returning by fax (1-800-FDA-0178) or by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787). If there is no online internet access such reports must be made by calling 1-800-FDA-1088; (2) that such reports include in the description section of the MedWatch Form 3500 the words "Peramivir EUA" and include unique identifier(s) (e.g., Peramivir Request number(s)); and (3) that such reports are made within seven calendar days from the onset of the event. Such Health Care Providers or their designees will conduct any follow-up requested by FDA and/or CDC.

C.4. Health Care Providers will prescribe and/or administer authorized peramivir only for the treatment of certain patients with suspected or laboratory confirmed 2009 H1N1 infection or infection due to nonsubtypable influenza A virus suspected to be 2009 H1N1 based on community epidemiology. Specifically, peramivir is authorized only for the following patients who are admitted to a hospital and under the care or consultation of a licensed clinician (skilled in the diagnosis and management of patients with potentially life-threatening illness and the ability to recognize and manage medication-related adverse events):

a. Adult patients for whom therapy with an IV agent is clinically appropriate, based upon one or more of the following reasons:
   (i) patient not responding to either oral or inhaled antiviral therapy, or
   (ii) drug delivery by a route other than IV (e.g., enteral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible, or

(iii) the clinician judges IV therapy is appropriate due to other circumstances.

b. Pediatric patients for whom an IV agent is clinically appropriate because:

(i) patient not responding to either oral or inhaled antiviral therapy, or

(ii) drug delivery by a route other than IV (e.g., enteral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible.

C.5. Health Care Providers will ensure that patients with known or suspected renal insufficiency have creatinine clearance determined prior to peramivir dose calculation and first administration. (See Fact Sheet For Health Care Providers; Dosage and Administration for Impaired Renal Function Dosing).

C.6. Health Care Providers prescribing and/or administering authorized peramivir will ensure that patients with history of severe allergic reaction to any other neuraminidase inhibitor (zanamivir or oseltamivir) or any ingredient of peramivir will not receive authorized peramivir. (See Fact Sheet for Health Care Providers; Product Description.)

C.7. Health Care Providers will only make available additional written information relating to the emergency use of authorized peramivir to the extent that it is consistent with and does not exceed the terms of this letter of authorization (including the facts sheets referenced in Section II of this letter).

C.8. Heath Care Providers will make available to FDA and/or CDC upon request any records maintained in connection with this letter. Upon request, Health Care Providers will report to FDA and/or CDC information with respect to the emergency use of authorized peramivir.

D. BioCryst

D.1. BioCryst will post on its website the following statement: "For information about the FDA-authorized emergency use of peramivir, please see *www.cdc.gov/h1n1flu/eua*."

D.2. BioCryst will distribute authorized peramivir only to CDC and/or its designees subject to the terms and conditions of this letter.

D.3 BioCryst will contact FDA concerning the need for any FDA review and approval before any changes are made to the manufacturing, packaging, and labeling processes authorized as of the date of this letter.

D.4. BioCryst (or anyone acting on behalf of BioCryst) will not represent authorized peramivir in a promotional context or otherwise promote authorized peramivir.

D.5. BioCryst will make available to FDA and (as reasonably appropriate) CDC upon request any records maintained in connection with this letter. Upon request, BioCryst will report to FDA and/or (as reasonably appropriate) CDC information with respect to the emergency use of authorized peramivir.

The emergency use of authorized peramivir as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Food and Drugs

[1] FDA is authorizing the emergency use of peramivir administered intravenously for treatment of 2009 H1N1 in certain adult and pediatric patients as described in the scope section of this letter (Setion II of thie letter). For ease of reference, this letter of authorization will also use the term "authorized peramivir."

[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

[3] The activites with respect to authorized peramivir refer to requesting, preparing, prescribing, and/or administering authorized peramivir, unless otherwise specified.

Dated: April 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8604 Filed 4–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0277]

Authorization of Emergency Use of Certain In Vitro Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of 10 Emergency Use Authorizations (EUAs) (the Authorizations) several of which were amended after initial issuance, for certain in vitro diagnostic devices. FDA also is announcing an amendment to the EUA for the Centers for Disease Control and Prevention (CDC) Swine Influenza Virus Real-time RT-PCR Detection Panel authorized on April 27, 2009. FDA is issuing the Authorizations and amendments thereto under the Federal Food, Drug, and Cosmetic Act (the act). The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostics. The Authorizations follow

the determination by the Acting Secretary of the U.S. Department of Health and Human Services, Charles E. Johnson (the Acting Secretary), that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A, or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics, accompanied by emergency use information subject to the terms of any authorization issued under the Federal Food, Drug, and Cosmetic Act (the act). The Authorizations, which include explanations of the reasons for their issuance or reissuance, are reprinted in this document.

DATES: See the **SUPPLEMENTARY INFORMATION** section of this document for effective dates of the Authorizations.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization(s) may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: RADM Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. 360bbb-3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a public health emergency that affects, or has a significant potential to affect, national security, and that involves biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency justifying the authorization based on one of the following grounds:

(1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;

(2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or

(3) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d) that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in a declared emergency. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the act (21 U.S.C. 355, 360(k), and 360e, respectively) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the National Institutes of Health (NIH) and the CDC (to the extent feasible and appropriate given the circumstances of the emergency), FDA[1] concludes:

(1) that an agent specified in a declaration of emergency can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that:

- the product may be effective in diagnosing, treating, or preventing—
  - such disease or condition; or
  - a serious or life-threatening disease or condition caused by a product authorized under section 564 of the act, approved or cleared under the act, or licensed under Section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and
- the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;
  - that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and
  - that such other criteria as the Secretary may by regulation prescribe are satisfied.

No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the act. Because the statute is self-executing, FDA does not require regulations or guidance to implement the EUA authority. However, FDA published guidance in July 2007 entitled "Emergency Use Authorization of Medical Products" to provide more information for stakeholders and the public about the EUA authority and the agency's process for the consideration of EUA requests.

II. EUA Request for Certain In Vitro Diagnostic Products

On April 26, 2009, under section 564(b)(1)(C) of the act, the Acting Secretary determined that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A, or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. The determination has been renewed. On April 26, 2009, under section 564(b) of the act, and on the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of certain in vitro diagnostics for detection of Swine Influenza A (2009 H1N1 flu), accompanied by emergency use information subject to the terms of any authorization issued under section

[1] The Secretary has delegated his authority to issue an EUA under section 564 of the act to the Commissioner of Food and Drugs.

564(a) of the act. Notice of the determination and the declaration of the Acting Secretary was published in the **Federal Register** on August 4, 2009 (74 FR 38628).

(1) On July 23, 2009, in response to a request from Focus Diagnostics, Inc., FDA issued an EUA for the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR IVD device with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. In response to requests from Focus Diagnostics, Inc., FDA amended the Authorization letter and reissued the Authorization letter in its entirety two times. On August 14, 2009, FDA amended the Authorization letter to authorize certain changes to the authorized labeling and permit future changes to the authorized labeling with written permission from FDA. On December 18, 2009, FDA amended the Authorization letter to authorize use of additional upper respiratory tract samples and lower respiratory tract specimens, and for other reasons. The Authorization letter, as amended and reissued on December 18, 2009, which includes an explanation for its reissuance, is reprinted in this document. Because the December 2009 amendment incorporated both the July 2009 Authorization letter and the August 2009 amendment to the Authorization letter in their entirety, the original July 2009 Authorization letter and the August 2009 amendment to the Authorization letter are not reprinted in this document.

(2) On August 24, 2009, in response to a request from the Department of Defense (DOD), FDA issued an EUA for the CDC Swine Influenza Virus Real-time rRT-PCR Detection Panel on JBAIDS with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. On December 18, 2009, in response to a request from DOD, FDA amended the Authorization letter to authorize use of additional upper respiratory tract samples and lower respiratory tract specimens, and for other reasons, and reissued the Authorization letter in its entirety. The Authorization letter, as amended and reissued on December 18, 2009, which includes an explanation for its reissuance, is reprinted in this document. The original August 2009 Authorization letter is not reprinted in this document.

(3) On October 9, 2009, in response to a request from Diatherix Laboratories, Inc., FDA issued an EUA for the Diatherix H1N1-09 Influenza Test with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(4) On October 16, 2009, in response to a request from Focus Diagnostics, Inc., FDA issued an EUA for the Focus Diagnostics Simplexa Influenza A H1N1 (2009) with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. On December 18, 2009, in response to a request from Focus Diagnostics, Inc., FDA amended the Authorization letter to authorize use of additional upper respiratory tract samples and lower respiratory tract specimens, and for other reasons, and reissued the Authorization letter in its entirety. The Authorization letter, as amended and reissued on December 18, 2009, which includes an explanation for its reissuance, is reprinted in this document. The original October 2009 Authorization letter is not reprinted in this document.

(5) On October 27, 2009, in response to a request from Prodesse, Inc., FDA issued an EUA for the Prodesse ProFlu-ST Influenza A Subtyping Assay with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(6) On November 13, 2009, in response to a request from Epoch BioSciences, FDA issued an EUA for the ELITech Molecular Diagnostics 2009-H1N1 Influenza A Virus Real Time RT-PCR test with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(7) On November 13, 2009, in response to a request from Roche Diagnostics GmbH, FDA issued an EUA for the Roche RealTime ready Influenza A/H1N1 Detection Set with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(8) On December 9, 2009, in response to a request from DxNA, LLC, FDA issued an EUA for the GeneSTAT 2009 A/H1N1 Influenza Test with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(9) On December 16, 2009, in response to a request from TessArae, LLC, FDA issued an EUA for the TessArray Resequencing Influenza A Microarray Detection Panel with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

(10) On April 27, 2009, in response to a request from CDC, FDA issued an EUA for the CDC Swine Influenza Virus Real-time rRT-PCR Detection Panel. On May 2, 2009, in response to a request from CDC, FDA amended the Authorization letter to authorize the use of different sample types and reagents, and on August 4, 2009, notice of the initial Authorization and the amended Authorization was published in the **Federal Register** (74 FR 38636, August 4, 2009). On December 18, 2009, in response to a request from CDC, FDA amended the Authorization letter again to authorize the use of an additional upper respiratory tract specimen and use of lower respiratory tract specimens, to remove the word "presumptive" from the Intended Use, to allow the use of the CDC Swine Influenza Virus Real-time rRT-PCR Detection Panel as a stand alone test, and for other reasons. FDA reissued the Authorization letter in its entirety. The Authorization letter, as amended and reissued on December 18, 2009, which includes an explanation for its reissuance, is reprinted in this document.

(11) On December 24, 2009, in response to a request from Cepheid, FDA issued an EUA for the Cepheid Xpert Flu A Panel with certain written information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. The Authorization letter, which includes an explanation for its issuance, is reprinted in this document.

III. Effective Dates of the Authorizations

The Authorizations are effective as follows:

(1) The Authorization for Focus Diagnostics Influenza A H1N1 (2009)

Real-Time RT-PCR IVD device is effective as of July 23, 2009;

(2) The Authorization for CDC Swine Influenza Virus Real-time rRT-PCR Detection Panel on the Joint Biological Agent Identification and Diagnostic System Instrument (CDC Swine Influenza Virus Real-time rRT-PCR Detection Panel JBAIDS) is effective as of August 24, 2009;

(3) The Authorization for Diatherix H1N1-09 Influenza Test is effective as of October 9, 2009;

(4) The Authorization for Focus Diagnostics Simplexa Influenza A H1N1 (2009) is effective as of October 16, 2009;

(5) The Authorization for Prodesse ProFlu-ST Influenza A Subtyping Assay is effective as of October 27, 2009;

(6) The Authorization for ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test by Associated Regional and University Pathologists Laboratories is effective as of November 13, 2009;

(7) The Authorization for Roche RealTime ready Influenza A/H1N1 Detection Set is effective as of November 13, 2009;

(8) The Authorization for GeneSTAT 2009 A/H1N1 Influenza Test is effective as of December 9, 2009;

(9) The Authorization for TessArray Resequencing Influenza A Microarray Detection Panel is effective as of December 16, 2009;

(10) The amendment to the EUA for the CDC Swine Influenza Virus Real-time rRT-PCR Detection Panel is effective as of December 18, 2009; and

(11) The Authorization for Cepheid Xpert Flu A Panel is effective as of December 24, 2009.

IV. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the Internet at *http://www.regulations.gov*.

V. The Authorizations

Having concluded that the criteria for issuance of the Authorizations, one as amended, under section 564(c) of the act are met, FDA has authorized the emergency use of certain in vitro diagnostic devices.

(1) The Authorization for Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR IVD device issued on July 23, 2009, as amended and reissued in its entirety on December 18, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

John G. R. Hurrell, Ph.D.
Vice President and General Manager
Focus Diagnostics, Inc.
11331 Valley View Street
Cypress, CA 90630

Dear Dr. Hurrell:

On July 23, 2009 FDA issued a letter authorizing the emergency use of the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR (Flu A H1N1 (2009) rRT-PCR) for the diagnosis of 2009 H1N1 influenza virus infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a, to perform high complexity tests (CLIA High Complexity Laboratories). On November 20, 2009, Focus submitted a request for an amendment to the Emergency Use Authorization. In response to that request, the letter authorizing emergency use of the Flu A H1N1 (2009) rRT-PCR is being reissued in its entirety with the amendments incorporated.[1]

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. §247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[2] Pursuant to section 564(b) of the Act (21 U.S.C. §360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. §360bbb-3(c)) are met, I am authorizing the emergency use of the Flu A H1N1 (2009) rRT-PCR for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Flu A H1N1 (2009) rRT-PCR for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

(2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Flu A H1N1 (2009) rRT-PCR may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the Flu A H1N1 (2009) rRT-PCR, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

(3) There is no adequate, approved, and available alternative to the emergency use of the Flu A H1N1 (2009) rRT-PCR for the diagnosis of 2009 H1N1 influenza virus infection.[3]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Flu A H1N1 (2009) rRT-PCR for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized Flu A H1N1 (2009) rRT-PCR:

The Focus Diagnostics Influenza A H1N1 (2009) Real Time RT-PCR test is a real-time RT-PCR assay that utilizes fluorogenic hydrolysis (Taqman®) probes for use on the ABI 7500 Real-Time PCR instrument for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in upper respiratory tract specimens (such as nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal/throat swabs (NPS/TS)), and lower respiratory tract specimens (such as broncheoalveolar lavage (BAL), bronchial aspirate (BA); bronchial wash (BW); endotracheal aspirate (EA); endotracheal wash (EW); tracheal aspirate (TA), and lung tissue) from patients with signs and symptoms of respiratory infection. The assay is composed of two principal steps: (1) extraction of RNA from patient specimens, (2) one-step reverse transcription and PCR amplification with human influenza A virus and the 2009 H1N1 influenza virus-specific primers and real-time detection with influenza A and 2009 H1N1 influenza virus-specific probes.

The Flu A H1N1 (2009) rRT-PCR includes the following primer and probe sets:

- **FLU A** detects a well-conserved region of the matrix gene from influenza A viruses in both human influenza A virus and 2009 H1N1 influenza virus.
- **SWINE 1 and SWINE 2** specifically detect two separate regions of the 2009 H1N1 influenza virus strain's HA gene. The SWINE 1 and SWINE 2 reactions are not multiplexed and are performed in parallel in separate wells.

The Flu A H1N1 (2009) rRT-PCR also includes control materials:

- **Internal Positive Amplification Control (IPC):** Exogenous IPC Reagent available separately from Applied Biosystems (Catalog No. 4308323). An internal positive control is included to confirm the absence of PCR inhibition.
- **External Positive Control**: Swine influenza virus stock (ATCC VR-897) diluted at 1:800.
- **External Negative Control**: Nuclease free water.

The above described Flu A H1N1 (2009) rRT-PCR test, when labeled consistently with the labeling authorized by FDA, entitled Influenza A H1N1 (2009) Real-Time RT-PCR Package Insert, (see *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by CLIA High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Flu A H1N1 (2009) rRT-PCR test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet For Healthcare Providers: Interpreting Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR Test Results**
- **Fact Sheet For Patients: Understanding The Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR Test Results**

As described in section IV below, Focus Diagnostics and CLIA High Complexity Laboratories are also authorized to make available additional information relating to the emergency use of the authorized Flu A H1N1 (2009) rRT-PCR that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Flu A H1N1 (2009) rRT-PCR in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Flu A H1N1 (2009) rRT-PCR may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized Flu A H1N1 (2009) rRT-PCR when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Flu A H1N1 (2009) rRT-PCR under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Flu A H1N1 (2009) rRT-PCR described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Flu A H1N1 (2009) rRT-PCR during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Flu A H1N1 (2009) rRT-PCR.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Focus Diagnostics

A. Focus Diagnostics will distribute the Flu A H1N1 (2009) rRT-PCR with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. Focus Diagnostics will provide to the CLIA High Complexity Laboratories the authorized Flu A H1N1 (2009) rRT-PCR Fact Sheet for Healthcare Providers and the authorized Flu A H1N1 (2009) rRT-PCR Fact Sheet for Patients.

C. Focus Diagnostics will make available on its website the authorized Flu A H1N1 (2009) rRT-PCR Fact Sheet for Healthcare Providers and the authorized Flu A H1N1 (2009) rRT-PCR Fact Sheet for Patients.

D. Focus Diagnostics will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized Flu A H1N1 (2009) rRT-PCR shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the Flu A H1N1 (2009) rRT-PCR shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. §360bbb-3(b)(1); and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the authorized Flu A H1N1 (2009) rRT-PCR may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. Focus Diagnostics will ensure CLIA High Complexity Laboratories using the authorized Flu A H1N1 (2009) rRT-PCR have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. Focus Diagnostics will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, Focus Diagnostics will maintain records of device usage.

K. Focus Diagnostics will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which Focus Diagnostics becomes aware.

CLIA High Complexity Laboratories

L. CLIA High Complexity Laboratories will include with reports of the results of the Flu A H1N1 (2009) rRT-PCR the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

M. CLIA High Complexity Laboratories will perform the assay on an Applied Biosystems 7500 Fast Dx Real-time PCR instrument or the RUO marketed Applied Biosystems 7500 Real-time PCR instrument.

N. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

O. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to Focus Diagnostics any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

Focus Diagnostics and CLIA High Complexity Laboratories

P. Focus Diagnostics is authorized to make available additional information relating to the emergency use of the authorized Flu A H1N1 (2009) rRT-PCR that is consistent with, and does not exceed, the terms of this letter of authorization.

Q. Only Focus Diagnostics may request changes to the authorized Fact Sheet for Healthcare Providers or the authorized Flu A H1N1 (2009) rRT-PCR Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

R. Focus Diagnostics will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized Flu A H1N1 (2009) rRT-PCR as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] The amendments to the July 23, 2009 letter authorize use of additional upper respiratory tract samples, such as nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal / throat swabs (NPS/TS), and lower respiratory tract specimens, such as broncheoalveolar lavage (BAL), bronchial aspirate (BA), bronchial wash (BW), endotracheal aspirate (EA), endotracheal wash (EW), tracheal aspirate (TA), and lung tissue. There are also corrections to the waiver section and minor wording changes made to be consistent with more recently issued Emergency Use Authorizations for in vitro diagnostic devices.
[2] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[3] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(2) The Authorization for the CDC Swine Influenza Virus Real-time rRT-PCR Detection Panel on JBAIDS issued on August 24, 2009, as amended and reissued in its entirety on December 18, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Robert E. Miller, Ph.D., RAC
Director
United States Army Medical Material Development Activity
1430 Veterans Drive
Ft. Detrick, Maryland 21702-9232

Dear Dr. Miller:

On August 24, 2009, FDA issued a letter authorizing the emergency use of the CDC swH1N1 (swine) Influenza Virus Real-time RT-PCR Detection Panel on the Joint Biological Agent Identification and Diagnostic System (JBAIDS)[1] Instrument (rRT-PCR Swine Flu Panel on JBAIDS) for the diagnosis of 2009 H1N1 influenza virus infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by qualified Department of Defense (DoD) laboratories that are equipped with the JBAIDS instruments. On November 16, 2009, the Office of the Surgeon General, Department of the Army submitted a request for an amendment to the Emergency Use Authorization. In response to that request, the letter authorizing emergency use of the rRT-PCR Swine Flu Panel on JBAIDS is being reissued in its entirety with the amendments, as requested by the Office of the Surgeon General, Department of the Army, incorporated.[2]

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[3] Pursuant to section 564(b) of the Act (21 U.S.C. §360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. §360bbb-3(c)) are met, I am authorizing the emergency use of the rRT-PCR Swine Flu Panel on JBAIDS (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the rRT-PCR Swine Flu Panel on JBAIDS for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

(2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the rRT-PCR Swine Flu Panel on JBAIDS may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the rRT-PCR Swine Flu Panel on JBAIDS, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such products; and

(3) There is no adequate, approved, and available alternative to the emergency use of the rRT-PCR Swine Flu Panel on JBAIDS for the diagnosis of 2009 H1N1 influenza virus infection.[4]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized rRT-PCR Swine Flu Panel on JBAIDS for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The authorized rRT-PCR Swine Flu Panel on JBAIDS:

rRT-PCR Swine Flu Panel on JBAIDS is a panel of oligonucleotide primers and dual-labeled hydrolysis (Taqman®) probes for use in the real-time RT-PCR assay on the Joint Biological Agent Identification and Diagnostic System (JBAIDS) instrument for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in upper respiratory tract specimens, such as nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal / throat swabs (NPS/TS), and lower respiratory tract specimens (LRTS), such as broncheoalveolar lavage (BAL), bronchial aspirate (BA), bronchial wash (BW), endotracheal aspirate (EA), endotracheal wash (EW), tracheal aspirate (TA), and lung tissue, from patients with signs and symptoms of respiratory infection and in viral culture.

The rRT-PCR Swine Flu Panel on JBAIDS includes the following primer and probe sets:
- **InfA** detects universal influenza A strains
- **swInfA** specifically detects swine influenza A strains (NP gene)
- **swH1** is specific for swine influenza A, subtype H1 (HA gene)

The rRT-PCR Swine Flu Panel on JBAIDS also includes control materials:
- **RNase P (RP)** detects human RNase P and is used as a positive control with human clinical specimens to indicate that adequate isolation of nucleic acid resulted from the extraction of the clinical specimen.
- **Swine Influenza Panel Real-Time RT-PCR Positive Control (SIPC)** is a positive control designed to react with all the primer and probe sets including RNase P.

The rRT-PCR Swine Flu Panel on JBAIDS requires the following hardware and software:
- **JBAIDS Instrument** is a real-time polymerase chain reaction (PCR) instrument developed as part of a biothreat detection system for the Department of Defense (DoD). It comes with a ruggedized laptop computer loaded with specific, user-friendly system software.
- **JBAIDS Influenza Specific Macro** is a compact disc (CD) provided by the JBAIDS Training Facility that contains the Influenza specific macro with Operating Instructions.

The rRT-PCR Swine Flu Panel on JBAIDS requires the use of the following nucleic acid extraction kit:
- **Qiagen QIAamp Viral RNA Mini kit and protocol**

The above described rRT-PCR Swine Flu Panel on JBAIDS, when labeled consistently with the labeling authorized by FDA, entitled CDC swH1N1 (swine) Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) on JBAIDS (see *http://www.fda.gov/medicaldevices/Safety/emergencysituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by qualified Department of Defense (DoD) laboratories[5] that are equipped with the JBAIDS instruments under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described rRT-PCR Swine Flu Panel on JBAIDS is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- Fact Sheet For Healthcare Providers: Interpreting Test Results Obtained with the CDC swH1N1 (swine) Influenza Virus Real-time RT-PCR Detection Panel on the Joint Biological Agent Identification and Diagnostic System (JBAIDS) Instrument
- Fact Sheet For Patients: Understanding Test Results Obtained with the CDC swH1N1 (swine) Influenza Virus Real-time RT-PCR Detection Panel on the Joint Biological Agent Identification and Diagnostic System (JBAIDS) Instrument

As described in section IV below, DoD and JBAIDS are also authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Swine Flu Panel on JBAIDS that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized rRT-PCR Swine Flu Panel on JBAIDS in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized rRT-PCR Swine Flu Panel on JBAIDS may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized rRT-PCR Swine Flu Panel on JBAIDS, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized rRT-PCR Swine Flu Panel on JBAIDS under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the rRT-PCR Swine Flu Panel on JBAIDS described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the rRT-PCR Swine Flu Panel on JBAIDS during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the rRT-PCR Swine Flu Panel on JBAIDS
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

DoD/ Joint Project Management Office (JPMO), Chemical Biological Medical Systems (CBMS)

A. DoD/JPMO,CBMS will distribute the rRT-PCR Swine Flu Panel on JBAIDS with the authorized labeling, as may be revised with written permission of FDA, only to qualified DoD laboratories that are equipped with the JBAIDS instruments.

B. DoD/JPMO,CBMS will provide to the qualified DoD laboratories the authorized rRT-PCR Swine Flu Panel on JBAIDS Fact Sheets for Healthcare Providers, and the authorized rRT-PCR Swine Flu Panel on JBAIDS Fact Sheets for Patients.

C. DoD/JPMO,CBMS will make available on its website the authorized rRT-PCR Swine Flu Panel on JBAIDS Fact Sheets for Healthcare Providers, and the authorized rRT-PCR Swine Flu Panel on JBAIDS Fact Sheets for Patients.

D. DoD/JPMO,CBMS will ensure that the state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.

E. DoD/JPMO,CBMS will ensure that qualified DoD laboratories using the authorized rRT-PCR Swine Flu Panel on BAIDS have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

F. DoD/JPMO,CBMS will track adverse events and report to FDA as required under 21 CFT part 803..

G. Through a process of inventory control, DoD/JPMO,CBMS will maintain records of device usage.

H. DoD/JPMO,CBMS will collect information on the performance of the assay, to include the incidence of false positive and negative results.

Qualified DoD Laboratories

I. Qualified DoD laboratories will include with reports of the results of the rRT-PCR Swine Flu Panel on JBAIDS, the authorized Fact Sheets for Healthcare Providers and the authorized Fact Sheet for Patients.

J. Qualified DoD laboratories will perform the assay on a JBAIDS instrument.

K. Qualified DoD laboratories will have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

L. Qualified DoD laboratories will collect information on the performance of the assay, and report to DoD/JPMO,CBMS any suspected occurrence of false positive or false negative results of which Qualified DoD laboratories become aware.

DoD/ Joint Project Management Office (JPMO), Chemical Biological Medical Systems (CBMS) and Qualified DoD Laboratories

M. DoD/JPMO,CBMS is authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Swine Flu Panel on JBAIDS that is consistent with, and does not exceed, the terms of this letter of authorization.

N. Only DoD/JPMO,CBMS may request changes to the authorized rRT-PCR Swine Flu Panel on JBAIDS Fact Sheet for Healthcare Providers or the authorized rRT-PCR Swine Flu Panel on JBAIDS Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

O. DoD/JPMO,CBMS and the qualified DoD laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized rRT-PCR Swine Flu Panel on JBAIDS as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] For ease of reference, this letter will use the term the "rRT-PCR Swine Flu Panel on JBAIDS."
[2] The amendments to the August 24, 2009 letter authorize use of additional upper respiratory tract samples, such as nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal / throat swabs (NPS/TS), and lower respiratory tract specimens, such as broncheoalveolar lavage (BAL), bronchial aspirate (BA), bronchial wash (BW), endotracheal aspirate (EA), endotracheal wash (EW), tracheal aspirate (TA), and lung tissue. There are also corrections to the waiver section, an additional condition for DoD Laboratories, and minor wording changes made to be consistent with more recently issued Emergency Use Authorizations for in vitro diagnostic devices.
[3] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[4] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[5] All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by JBAIDS instructors or designees prior to use. Use of this device is limited to qualified Department of Defense (DoD) laboratories equipped with the JBAIDS instruments. See "Conditions of Authorization" below.

(3) The Authorization for Diatherix H1N1-09 Influenza Test issued on October 9, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Dennis L. Grimaud
Chairman and Chief Executive Officer
DIATHERIX Laboratories, Inc.
601 Genome Way, Suite 4208
Huntsville, AL 35806

Dear Mr.Grimaud:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the DIATHERIX H1N1-09 Influenza Test for the diagnosis of 2009 H1N1 influenza virus infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), by DIATHERIX Laboratories, Inc., a CLIA High Complexity Laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a, to perform high complexity tests.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. §247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. §360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. §360bbb-3(c)) are met, I am authorizing the emergency use of the DIATHERIX H1N1-09 Influenza Test (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the DIATHERIX H1N1-09 Influenza Test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The recently isolated 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus.

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the DIATHERIX H1N1-09 Influenza Test may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the DIATHERIX H1N1-09 Influenza Test, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the DIATHERIX H1N1-09 Influenza Test for the diagnosis of 2009 H1N1 influenza virus infection.[2]

Therefore, I have concluded that the emergency use of the DIATHERIX H1N1-09 Influenza Test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the above criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized DIATHERIX H1N1-09 Influenza Test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized DIATHERIX H1N1-09 Influenza Test:

The DIATHERIX H1N1-09 Influenza Test is a multiplexed molecular diagnostic assay that performs target enriched multiplex PCR nucleic acid amplification on the ABI 9700 thermocycler followed by probe hybridization and subsequent detection on the Qiagen Luminex LiquiChip 100 platform for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, and nasopharyngeal aspirates specimens from patients with signs and symptoms of respiratory infection.

The DIATHERIX H1N1-09 Influenza Test includes the following primer and probe sets:

- **H1 (H109C):** a total of 4 primers designed for nested PCR to detect the presence of the hemagglutinin gene specifically found in the 2009 H1N1 influenza A virus.
- **N1 (N109B):** a total of 4 primers designed for nested PCR to detect the presence of the neuraminidase gene specifically found in the 2009 H1N1 influenza A virus.
- **Probes:** each amplicon is hybridized to complementary capture probes (H109C De and N109B De, respectively), which are covalently coupled to color coded beads detectable by the Luminex technology.

The DIATHERIX H1N1-09 Influenza Test also includes the following control materials:

- **ABM, extraction positive control:** *Acinetobacter baumannii*, ATCC strain 19606, will be used as a culture stock diluted and subjected to extraction as an additional sample during each batch of patient specimen extractions to demonstrate the effectiveness of the extraction method (rule out false negatives due to extraction failure and false positives due to carryover contamination).
- **PCR Blank, negative control:** A water blank will be run as an additional PCR sample during each batch of patient specimen testing to demonstrate that no carryover contamination has occurred during the PCR process (rule out false positives).
- **PCR positive control:** Nucleic acid from *Haemophilus influenzae*, ATCC strain 10211, will be run as a separate PCR sample with each batch run of patient specimens. The PCR positive control demonstrates the effectiveness of the PCR reaction to amplify targets in the assay (rule out PCR false negatives).
- **PCR positive internal control:** DNA from *Acinetobacter baumannii* ATCC strain 19606 will be added to each PCR to act as an internal amplification control. For each sample, if either the ABM target or any other target is positive, the PCR passes. If both ABM and all other targets fail to produce a positive signal, the PCR has failed and must be repeated.

The DIATHERIX H1N1-09 Influenza Test requires the following hardware with corresponding software:

- **Thermo Fisher Kingfisher 96, software version 2.6.2:** nucleic acid extraction instrument.
- **ABI 9700 Thermocycler, software version 3.09:** PCR amplification instrument.
- **Qiagen Luminex LiquiChip 100, software version 2.3.182:** bead detection instrumentation.

The DIATHERIX H1N1-09 Influenza Test requires the use of the following additional reagent kits:

- **Starplex Collection Kit** (tube, swab, medium, biohazard bag and shipping box) (Catalog number: SP132-FL75).
- **Scigenix MagnetX Extraction Kit** (Catalog number: R2-2400-DTX-I0).
- **Qiagen OneStep RT-PCR Kit** (Catalog number: 210212).
- **BioRad Luminex beads** (Catalog number: 171506xx).

The above described DIATHERIX H1N1-09 Influenza Test, when labeled consistently with the labeling authorized by FDA, entitled Diatherix Laboratories H1N1-09 Influenza Test Package Insert, as may be revised with written permission of FDA, is authorized to be used by DIATHERIX Laboratories, Inc.,[3] under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described DIATHERIX H1N1-09 Influenza Test is authorized to be accompanied by the following information pertaining to the emergency use, which are authorized to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Interpretation of the DIATHERIX H1N1-09 Influenza Virus Test Results
- Fact Sheet for Patients: Understanding the DIATHERIX H1N1-09 Influenza Virus Test Results

As described in section IV below, DIATHERIX Laboratories, Inc., is also authorized to make available additional information relating to the emergency use of the authorized DIATHERIX H1N1-09 Influenza Test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized DIATHERIX H1N1-09 Influenza Test in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized DIATHERIX H1N1-09 Influenza Test may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized DIATHERIX H1N1-09 Influenza Test, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized DIATHERIX H1N1-09 Influenza Test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS' determination under section 564(b)(1)(C) described above and the Secretary of HHS' corresponding declaration under section 564(b)(1), the DIATHERIX H1N1-09 Influenza Test described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the DIATHERIX H1N1-09 Influenza Test during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, and storage of the DIATHERIX H1N1-09 Influenza Test.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

DIATHERIX Laboratories, Inc.

A. DIATHERIX Laboratories, Inc., will not sell or distribute the DIATHERIX H1N1-09 Influenza Test to other laboratories.

B. DIATHERIX Laboratories, Inc., will include with reports of the results of the DIATHERIX H1N1-09 Influenza Test the authorized DIATHERIX H1N1-09 Influenza Test Fact Sheets for Healthcare Providers and the authorized DIATHERIX H1N1-09 Influenza Test Fact Sheets for Patients.

C. DIATHERIX Laboratories, Inc., will make available on its Web site the authorized DIATHERIX H1N1-09 Influenza Test Fact Sheets for Healthcare Providers and the authorized DIATHERIX H1N1-09 Influenza Test Fact Sheets for Patients.

D. DIATHERIX Laboratories, Inc., will clearly and conspicuously state on reports of the results of the DIATHERIX H1N1-09 Influenza Test that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other pathogen.

E. DIATHERIX Laboratories, Inc., will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

F. All advertising and promotional descriptive printed matter relating to the use of the DIATHERIX H1N1-09 Influenza Test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

G. All advertising and promotional descriptive printed matter relating to the use of the DIATHERIX H1N1-09 Influenza Test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. §360bbb-3(b)(1); and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

H. No advertising or promotional descriptive printed matter relating to the use of the DIATHERIX H1N1-09 Influenza Test assay may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

I. DIATHERIX Laboratories, Inc., will have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

J. DIATHERIX Laboratories, Inc., will track adverse events and report to FDA as required under 21 CFR part 803.

K. Through a process of inventory control, DIATHERIX Laboratories, Inc., will maintain records of device usage.

L. DIATHERIX Laboratories, Inc., will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or negative results of which DIATHERIX Laboratories, Inc., becomes aware.

M. DIATHERIX Laboratories, Inc., is authorized to make available additional information relating to the emergency use of the authorized DIATHERIX H1N1-09 Influenza Test that is consistent with, and does not exceed, the terms of this letter of authorization.

N. Only DIATHERIX Laboratories, Inc., may request changes to the authorized DIATHERIX H1N1-09 Influenza Test Fact Sheet for Healthcare Providers or the authorized DIATHERIX H1N1-09 Influenza Test Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

O. DIATHERIX Laboratories, Inc., will perform the assay on the Applied Biosystems 9700 Thermocycler, coupled to the Qiagen Luminex LiquiChip 100 detection platform.

P. DIATHERIX Laboratories, Inc., will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized DIATHERIX H1N1-09 Influenza Test as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[3] This EUA does not authorize the DIATHERIX H1N1-09 Influenza Test to be sold or distributed to or used by other laboratories.

(4) The Authorization for the Focus Diagnostics Simplexa Influenza A H1N1 (2009) issued on October 16, 2009, as amended and reissued in its entirety on December 18, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

John G. R. Hurrell, Ph.D.
Vice President and General Manager
Focus Diagnostics, Inc.
11331 Valley View Street
Cypress, CA 90630

Dear Dr. Hurrell:

On October 16, 2009 FDA issued a letter authorizing the emergency use of the Focus Diagnostics Simplexa™ Influenza A H1N1 (2009) (Simplexa™ Inf A H1N1-09) for the diagnosis of 2009 H1N1 influenza virus infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a, to perform high complexity tests (CLIA High Complexity Laboratories). On November 20, 2009, Focus submitted a request for an amendment to the Emergency Use Authorization. In response to that request, the letter authorizing emergency use of the Focus Diagnostics Simplexa™ Inf A H1N1-09) is being reissued in its entirety with the amendments incorporated.[1]

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. §247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[2] Pursuant to section 564(b) of the Act (21 U.S.C. §360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. §360bbb-3(c)) are met, I am authorizing the emergency use of the Simplexa™ Inf A H1N1-09 for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Simplexa™ Inf A H1N1-09 for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

(2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Simplexa™ Inf A H1N1-09 may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the Simplexa™ Inf A H1N1-09, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

(3) There is no adequate, approved, and available alternative to the emergency use of the Simplexa™ Inf A H1N1-09 for the diagnosis of 2009 H1N1 influenza virus infection.[3]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Simplexa™ Inf A H1N1-09 for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized Simplexa™ Inf A H1N1-09

The Focus Diagnostics Simplexa™ Inf A H1N1-09 is a real-time RT-PCR assay that utilizes a fluorescent probe-primer for use on the 3M Integrated Cycler for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in upper respiratory tract specimens (such as nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal/throat swabs (NPS/TS)), and lower respiratory tract specimens (such as broncheoalveolar lavage (BAL), bronchial aspirate (BA); bronchial wash (BW); endotracheal aspirate (EA); endotracheal wash (EW); tracheal aspirate (TA), and lung tissue) from patients with signs and symptoms of respiratory infection. The assay is composed of two principal steps: (1) extraction of RNA from patient specimens, (2) a bi-functional fluorescent probe-primer is used together with a reverse primer to amplify a specific target (for each analyte and internal control).

The Simplexa™ Inf A H1N1-09 kit includes the following primer sets:
- **FLUA** detects a well-conserved region of the matrix gene from influenza A viruses in both human influenza A virus and 2009 H1N1 influenza virus.
- **H1N1** specifically detects the 2009 H1N1 influenza virus strain's hemagglutinin gene. The FLUA and H1N1 reactions are multiplexed and are performed in the same well.

The Simplexa™ Inf A H1N1-09 kit also includes control materials:
- **Armored RNA Internal Control (AR IC)**: An internal positive control is included to confirm the absence of PCR inhibition.
- **External Positive Control**: Inactivated 2009 H1N1 Virus.
- **External Negative Control**: Nuclease free water.

The Simplexa™ Inf A H1N1-09 requires the following hardware with corresponding software:

- Roche MagNA Pure LC: Nucleic acid extraction instrument.
- 3M Integrated Cycler: PCR amplification instrument.

The Simplexa™ Inf A H1N1-09 requires the use of the following additional reagent kit:

- MagNA Pure LC Total Nucleic Acid Isolation Kit (Roche Cat. No 3038505001)

The above described Simplexa™ Inf A H1N1-09, when labeled consistently with the labeling authorized by FDA, entitled Simplexa™ Influenza A H1N1 (2009) Package Insert, (see *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by CLIA High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Simplexa™ Inf A H1N1-09 is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet For Healthcare Providers: Interpreting Focus Diagnostics Simplexa™ Influenza A H1N1 (2009) Test Results**
- **Fact Sheet For Patients: Understanding The Focus Diagnostics Simplexa™ Influenza A H1N1 (2009) Test Results**

As described in section IV below, Focus Diagnostics and CLIA High Complexity Laboratories are also authorized to make available additional information relating to the emergency use of the authorized Simplexa™ Inf A H1N1-09 that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Simplexa™ Inf A H1N1-09 in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Simplexa™ Inf A H1N1-09 may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized Simplexa™ Inf A H1N1-09 when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Simplexa™ Inf A H1N1-09 under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Simplexa™ Inf A H1N1-09 described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Simplexa™ Inf A H1N1-09 during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Simplexa™ Inf A H1N1-09.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Focus Diagnostics

A. Focus Diagnostics will distribute the Simplexa™ Inf A H1N1-09 with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. Focus Diagnostics will provide to the CLIA High Complexity Laboratories the authorized Simplexa™ Inf A H1N1-09 Fact Sheet for Healthcare Providers and the authorized Simplexa™ Inf A H1N1-09 Fact Sheet for Patients.

C. Focus Diagnostics will make available on its website the authorized Simplexa™ Inf A H1N1-09 Fact Sheet for Healthcare Providers and the authorized Simplexa™ Inf A H1N1-09 Fact Sheet for Patients.

D. Focus Diagnostics will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized Focus Diagnostics Simplexa™ Inf A H1N1-09 shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the Focus Diagnostics Simplexa™ Inf A H1N1-09 shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. §360bbb-3(b)(1); and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the authorized Simplexa™ Inf A H1N1-09 may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. Focus Diagnostics will ensure CLIA High Complexity Laboratories using the authorized Simplexa™ Inf A H1N1-09 have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. Focus Diagnostics will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, Focus Diagnostics will maintain records of device usage.

K. Focus Diagnostics will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which Focus Diagnostics becomes aware.

CLIA High Complexity Laboratories

L. CLIA High Complexity Laboratories will include with reports of the results of the Simplexa™ Inf A H1N1-09 the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

M. CLIA High Complexity Laboratories will perform the assay on a 3M Integrated Cycler as part of the Microfluidic Molecular System.

N. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

O. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to Focus Diagnostics any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

Focus Diagnostics and CLIA High Complexity Laboratories

P. Focus Diagnostics is authorized to make available additional information relating to the emergency use of the authorized Simplexa™ Inf A H1N1-09 that is consistent with, and does not exceed, the terms of this letter of authorization.

Q. Only Focus Diagnostics may request changes to the authorized Fact Sheet for Healthcare Providers or the authorized Simplexa™ Inf A H1N1-09 Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

R. Focus Diagnostics will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized Simplexa™ Inf A H1N1-09 as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] The amendments to the October 16, 2009 letter authorize use of additional upper respiratory tract samples, such as nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal / throat swabs (NPS/TS), and lower respiratory tract specimens, such as broncheoalveolar lavage (BAL), bronchial aspirate (BA), bronchial wash (BW), endotracheal aspirate (EA), endotracheal wash (EW), tracheal aspirate (TA), and lung tissue. There are also minor wording changes made to be consistent with more recently issued Emergency Use Authorizations for in vitro diagnostic devices.
[2] Memorandum, Determination Pursuant to §564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[3] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(5) The Authorization for Prodesse ProFlu-ST Influenza A Subtyping Assay issued on October 27, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Thomas M. Shannon
President and Chief Executive Officer
Prodesse, Inc.
W229 N1870 Westwood Drive
Waukesha, WI 53186

Dear Mr. Shannon:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Prodesse ProFlu-ST Influenza A Subtyping Assay for the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in individuals who are diagnosed with influenza A by currently available FDA-cleared or authorized devices, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by CLIA High Complexity Laboratories, which are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, to perform high complexity tests.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of the Department of Health and Human Services then declared an emergency justifying the authorization of the emergency use of certain *in vitro* diagnostics for the detection of Swine Influenza A (2009 H1N1 influenza virus), subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Prodesse ProFlu-ST Influenza A Subtyping Assay (Prodesse ProFlu-ST Assay)[2] for the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in individuals who are diagnosed with influenza A by currently available FDA-cleared or authorized devices, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Prodesse ProFlu-ST Assay for the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in individuals who are diagnosed with influenza A by currently available FDA-cleared or authorized devices, meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

(2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Prodesse ProFlu-ST Assay may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the Prodesse ProFlu-ST Assay, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

(3) There is no adequate, approved, and available alternative to the emergency use of the Prodesse ProFlu-ST Assay for the diagnosis of 2009 H1N1 influenza virus infection.[3,4]

Therefore, I have concluded that the emergency use of the Prodesse ProFlu-ST Assay for the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in individuals who are diagnosed with influenza A by currently available FDA-cleared or authorized devices meets the above criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the Prodesse ProFlu-ST Assay for the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in individuals who are diagnosed with influenza A by currently available FDA-cleared or authorized devices

The Authorized Prodesse ProFlu-ST Assay:

The Prodesse ProFlu-ST Assay is a multiplex real-time RT-PCR assay that utilizes fluorogenic hydrolysis (Taqman) probes for use on the Cepheid SmartCycler II instrument for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in nasopharyngeal swabs (NPS) from patients who are diagnosed with influenza A by currently available FDA-cleared or authorized devices. The assay is composed of two principal steps: (1) extraction of RNA from patient specimens, (2) one-step multiplex reverse transcription and PCR amplification with human seasonal influenza A virus subtypes and the 2009 H1N1 influenza virus specific primers, and real-time detection with seasonal influenza A virus subtypes and the 2009 H1N1 influenza virus specific probes.

The Prodesse ProFlu-ST Assay kit includes:
- ProFlu-ST Supermix that contains buffer, $MgCl_2$, nucleotides (dNTPs), Fast Start Taq polymerase, 4 pairs of oligonucleotide primers and 4 probes (4 sets)
- M-MLV Reverse Transcriptase
- RNase Inhibitor
- Influenza A subtyping RNA Control (pooled RNA control for all three detections)
- Internal Control

The Prodesse ProFlu-ST Assay includes the following primer and probe sets:
- **Seasonal H1** detects a conserved area of the seasonal influenza A/H1 Hemagglutinin (HA) gene.
- **Seasonal H3** detects a conserved area of the seasonal influenza A/H3 Hemagglutinin (HA) gene.
- **2009 H1N1 Influenza (S-OIV)** detects a conserved area of the 2009 H1N1 Influenza Nucleoprotein (NP) gene.
- **Internal RNA Control III** detects an 1158 base-long RNA transcript (MS2 Bacteriophage sequence) that is noncompetitive with the other targets of the ProFlu-ST Assay.

Control materials to be used with the Prodesse ProFlu-ST Assay include:
- **Internal RNA Control III (IC)** is a non-infectious *in vitro* transcribed 1158 base-long RNA (MS2 Bacteriophage sequence). The IC is incorporated into every sample and is carried through all steps of the procedure from nucleic acid isolation and purification through amplification to monitor for inhibitors present in the specimen or reaction tube. The IC also serves as a general process control ensuring that each step of the procedure is performed correctly, assay and instrument parameters are set correctly, and that general reagents are working.

- **Influenza A Subtyping RNA Control (PC)** is a pooled control containing three RNA transcripts, one each for the A/H1, A/H3, and A/2009 H1N1 detections targeted by the ProFlu-ST Assay. The PC does not go through nucleic acid isolation and purification, but is included during set-up of the RT-PCR reaction. The PC is required for each ProFlu-ST assay run. The PC in conjunction with the IC is used to verify reagent and system performance.
- **Negative Control (NC)** is blank viral transport medium used to monitor reagent and/or environmental contamination.
- **Extraction Control (EC)** is a previously characterized positive seasonal influenza A (H1 or H3) sample, positive 2009 H1N1 influenza sample, or a negative sample spiked with a well characterized seasonal influenza (H1 or H3) strain or 2009 H1N1 influenza strain. Good laboratory practice recommends including a positive extraction control in each nucleic acid isolation run. The extraction control should be treated like a sample during assay performance and analysis.

The Prodesse ProFlu-ST Assay requires the following instruments with corresponding software:

- The ProFlu-ST Assay utilizes the **Roche MagNA Pure LC System with software version 3.0.11** or the **bioMérieux NucliSENS easyMAG System with software version 1.0.1 or 2.0** for **nucleic acid extraction**.
- The ProFlu-ST Assay utilizes the **Cepheid SmartCycler II system with Dx software versions 1.7b, 3.0a, or 3.0b** for amplification and detection.

The above Prodesse ProFlu-ST Assay, when labeled consistently with the labeling agreed to by FDA and titled Prodesse ProFlu-ST Assay Instructions for Use, as may be revised with written permission of FDA, is authorized to be distributed to CLIA High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Prodesse ProFlu-ST Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- Fact Sheet For Healthcare Providers: Interpreting the Prodesse ProFlu-ST Assay Results
- Fact Sheet For Patients: Understanding the Prodesse ProFlu-ST Assay Results

As described in section IV below, Prodesse Inc. CLIA High Complexity Laboratories are also authorized to make available additional information relating to the emergency use of the authorized Prodesse ProFlu-ST Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Prodesse ProFlu-ST Assay in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results, outweigh the known and potential risks of such product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Prodesse ProFlu-ST Assay may be effective in the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized Prodesse ProFlu-ST Assay, when used to diagnose 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Prodesse ProFlu-ST Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Prodesse ProFlu-ST Assay described above is authorized to diagnose 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in individuals who are diagnosed with influenza A by currently available FDA-cleared or authorized devices.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Prodesse ProFlu-ST Assay during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Prodesse ProFlu-ST Assay.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Prodesse Inc.

A. Prodesse, Inc. will distribute the Prodesse ProFlu-ST Assay with the labeling agreed to by FDA and titled Prodesse ProFlu-ST Assay Instructions for Use, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. Prodesse, Inc. will provide to the CLIA High Complexity Laboratories the authorized Prodesse ProFlu-ST Assay Fact Sheet for Healthcare Providers and the authorized Prodesse ProFlu-ST Assay Fact Sheet for Patients.

C. Prodesse, Inc. will make available on its website the authorized Prodesse ProFlu-ST Assay Fact Sheet for Healthcare Providers and the authorized Prodesse ProFlu-ST Assay Fact Sheet for Patients.

D. Prodesse, Inc. will ensure that the state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.

E. As a condition of this EUA, all advertising and promotional descriptive printed matter relating to the use of the Prodesse ProFlu-ST Assay shall be consistent with the Fact Sheets and labeling agreed to by FDA and titled Prodesse ProFlu-ST Assay Instructions for Use, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. As a condition of this EUA, all advertising and promotional descriptive printed matter relating to the use of the Prodesse ProFlu-ST Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the diagnosis of 2009 H1N1 influenza virus infection in patients who have already been diagnosed with influenza A by currently available FDA-cleared or authorized devices;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. §360bbb-3(b)(1); and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the Prodesse ProFlu-ST Assay may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus, seasonal influenza A/H1 virus, or seasonal influenza A/H3 virus.

H. Prodesse, Inc. will ensure CLIA High Complexity Laboratories have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. Prodesse, Inc. will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, Prodesse, Inc. will maintain records of device usage.

K. Prodesse, Inc. will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which Prodesse, Inc becomes aware.

CLIA High Complexity Laboratories

L. CLIA High Complexity Laboratories will test a patient sample using the Prodesse ProFlu - ST Assay only when the patient sample has already been tested positive for Influenza A by a currently available FDA-cleared nucleic acid amplification technologies (NAAT)-based Influenza A device with high performance[5].

M. CLIA High Complexity Laboratories will include with reports of the results of the Prodesse ProFlu-ST Assay the authorized fact sheets for health care providers and the authorized fact sheets for patients.

N. CLIA High Complexity Laboratories will use the Roche MagNA Pure LC System or the bioMérieux NucliSENS easyMAG System for nucleic acid extraction, and perform the assay on the Cepheid SmartCycler II Real-time PCR instrument.

O. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

P. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to Prodesse, Inc. any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

Prodesse, Inc. and CLIA High Complexity Laboratories

Q. Prodesse, Inc. is authorized to make available additional information relating to the emergency use of the authorized Prodesse ProFlu-ST Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

R. Only Prodesse, Inc. may request changes to the authorized Prodesse ProFlu-AT Assay Fact Sheet for Healthcare Providers or the authorized Prodesse ProFlu-AT Assay Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

S. Prodesse, Inc. and CLIA High Complexity Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized Prodesse ProFlu-ST Assay as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] FDA is authorizing the emergency use of the Prodesse ProFlu-ST Assay as described in the scope section of this letter (Section II).
[3] Although there are no approved or cleared tests for the diagnosis of 2009 H1N1 influenza virus, to date, several devices have been FDA authorized under EUA to help address diagnostic needs. The information on the authorized devices is available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*.
[4] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[5] An FDA-cleared NAAT-based Influenza A device with high performance is an FDA cleared NAAT-based IVD device detecting Influenza A that demonstrates sensitivity (compared to viral culture) of at least 95% and specificity of at least 92% with a lower bound of 95% (two-sided) confidence interval exceeding 90% and that does not require culture confirmation for negative results.

(6) The Authorization for the ELITech Molecular Diagnostics 2009-H1N1 Influenza A Virus Real Time RT-PCR test issued on November 13, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Dr. Walt Mahoney
VP R&D and Operations
Managing Director
Epoch BioSciences
21720 23rd Drive S.E. Suite 150
Bothell, WA 98021

Dear Dr. Mahoney:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test by Associated Regional and University Pathologists (ARUP) Laboratories for the diagnosis of 2009 H1N1 influenza virus infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). ARUP Laboratories is a CLIA High Complexity Laboratory, certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a, to perform high complexity tests.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. §247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. §360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. §360bbb-3(c)) are met, I am authorizing the emergency use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus.

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection.[2]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR Test:

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test is a real-time reverse-transcription PCR for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, and nasal aspirates from patients with signs and symptoms of respiratory infection. Amplification and detection are accomplished using PCR primers and Pleiades hybridization probes manufactured by Epoch BioSciences, a Division of Wescor, Inc. The testing procedure consists of nucleic acid extraction on the Qiagen BioRobot 9604 instrument followed by real-time reverse-transcription PCR on the Applied Biosystems 7900HT Real-Time PCR System.

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test includes the following primer and probe sets:

- **2009H1:** detects the presence of the hemagglutinin (HA) gene specifically found in the 2009 H1N1 influenza A virus.
- **M1:** detects a conserved region of the Matrix Protein 1 (M1) gene that is present in seasonal and 2009-H1N1 influenza A viruses.
- **Bacteriophage MS2 Internal Control:** detects RNA sequence in whole bacteriophage MS2 that is noncompetitive with the 2009-H1N1 and M1 targets.

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test also includes the following control materials:

- **Bacteriophage MS2 Internal Control (IC)** is added to every patient sample and is carried through all steps of the procedure from nucleic acid isolation and purification through amplification to monitor for inhibitors present in the specimen or reaction tube. The IC also serves as a general process control ensuring that each step of the procedure was performed correctly, assay and instrument parameters were set correctly, and that general reagents were working.
- **Negative Control** consists of IC diluted with water and is taken through both nucleic acid extraction and PCR processes to demonstrate that no carryover contamination has occurred during the test process (rule out false positives caused by contamination). The Negative Control is incorporated into each batch of patient specimen processing.
- **Positive Controls** consists of separate RNA templates containing targets recognized by the 2009H1 and M1 detection systems. Each Positive Control is taken through both nucleic acid extraction and PCR processes to demonstrate that nucleic acid extraction and PCR are effective (rule out false negatives caused by test failure). The Positive Controls are incorporated into each batch of patient specimen processing.

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test requires the following hardware with corresponding software:

- Applied Biosystems 7900HT Real-Time PCR System with ABI Software: SDS 7900HT, v2.2.2.
- Qiagen BioRobot 9604 with QIAsoft 3.0 PLUS software.

The ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test requires the use of the following additional reagents/materials:

- Qiagen QuantiTect Probe RT-PCR Master mix (Qiagen Cat. No 204443)
- Consumables for Qiagen BioRobot 9604
- QIAamp Virus Biorobot 9604 Kit (Qiagen Cat. No 965662)
- RNase Inhibitor (Applied Biosystems Cat. No N8080119)
- Heat-labile Uracil N-Glycosylase (Roche Cat No 11775367001)
- MasterAmp 10X PCR Enhancer (Epicentre Cat No ME81210)

The above described ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test, when labeled consistently with the labeling authorized by FDA, entitled ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Package Insert (see *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by ARUP Laboratories,[3] under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test is authorized to be accompanied by the following information pertaining to the emergency use, which are authorized to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Interpretation of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR Test Results
- Fact Sheet for Patients: Understanding the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR Test Results

As described in section IV below, Epoch Biosciences, is also authorized to make available additional information relating to the emergency use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS' determination under section 564(b)(1)(C) described above and the Secretary of HHS' corresponding declaration under section 564(b)(1), the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Epoch Biosciences

A. Epoch Biosciences will distribute the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test with the authorized labeling, as may be revised with written permission of FDA, only to ARUP Laboratories.

B. Epoch Biosciences will provide to ARUP Laboratories the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Healthcare Providers and the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Patients.

C. Epoch Biosciences will make available on its website the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Healthcare Providers and the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Patients.

D. Epoch Biosciences will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. Epoch Biosciences will ensure ARUP Laboratories has a process in place for reporting test results to health care providers and federal, state, and/or local public health authorities, as appropriate.

F. Epoch Biosciences will track adverse events and report to FDA as required under 21 CFR part 803.

G. Through a process of inventory control, Epoch Biosciences will maintain records of device usage.

H. Epoch Biosciences will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which Epoch Biosciences becomes aware.

I. Epoch Biosciences is authorized to make available additional information relating to the emergency use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test that is consistent with, and does not exceed, the terms of this letter of authorization.

J. Only Epoch Biosciences may request changes to the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheet for Healthcare Providers or the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

ARUP Laboratories

K. ARUP Laboratories will include with reports of the results of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Healthcare Providers and the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Patients.

L. ARUP Laboratories will clearly and conspicuously state on reports of the results of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, respiratory syncytial virus (RSV) or any other pathogen.

M. ARUP Laboratories will use the Qiagen BioRobot 9604 for nucleic acid extraction and perform the assay on the Applied Biosystems 7900HT Real-time PCR instrument.

N. ARUP Laboratories will have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

O. ARUP Laboratories will collect information on the performance of the assay, and report to Epoch Biosciences any suspected occurrence of false positive or false negative results of which ARUP Laboratories becomes aware.

Epoch Biosciences and ARUP Laboratories

P. Epoch Biosciences and ARUP Laboratories will make available on their Web sites the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Healthcare Providers and the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test Fact Sheets for Patients.

Q. Epoch Biosciences and ARUP Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

R. All advertising and promotional descriptive printed matter relating to the use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

S. All advertising and promotional descriptive printed matter relating to the use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. §360bbb-3(b)(1); and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

T. No advertising or promotional descriptive printed matter relating to the use of the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

The emergency use of the authorized ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[3] This EUA does not authorize the ELITech Molecular Diagnostics 2009-H1N1 Influenza A virus Real-Time RT-PCR test to be sold or distributed to or used by other laboratories.

(7) The Authorization for the Roche RealTime ready Influenza A/H1N1 Detection Set issued on November 13, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Dr. Bernd Schmidt
Head of RAS Global Quality Management & Regulatory Affairs
Roche Diagnostics GmbH
Roche Applied Science
Nonnenwald 2
82377 Penzberg / Germany

Dear Dr. Schmidt:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Roche RealTime ready Influenza A/H1N1 Detection Set for the diagnosis of 2009 H1N1 influenza virus infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), by CLIA High Complexity Laboratories, which are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a, to perform high complexity tests.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. §247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. §360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. §360bbb-3(c)) are met, I am authorizing the emergency use of the Roche RealTime ready Influenza A/H1N1 Detection Set (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Roche RealTime ready Influenza A/H1N1 Detection Set for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus.

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Roche RealTime ready Influenza A/H1N1 Detection Set may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the Roche RealTime ready Influenza A/H1N1 Detection Set, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Roche RealTime ready Influenza A/H1N1 Detection Set for the diagnosis of 2009 H1N1 influenza virus infection.[2]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Roche RealTime ready Influenza A/H1N1 Detection Set for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized Roche RealTime ready Influenza A/H1N1 Detection Set:

The Roche RealTime ready Influenza A/H1N1 Detection Set is a real-time reverse-transcription PCR for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in nasal swabs, nasopharyngeal swabs, nasal washes, or nasal aspirates from patients with signs and symptoms of respiratory infection. The Roche RealTime ready Influenza A/H1N1 Detection Set is to be used in combination with the Roche RealTime ready RNA Virus Master kit which is a reaction mix for one-step RT-PCR using the LightCycler® system. The assay is composed of two principal steps: (1) extraction of RNA from patient specimens, (2) one-step reverse transcription and PCR amplification using fluorogenic hydrolysis (Taqman) probes for detection.

The Roche RealTime ready Influenza A/H1N1 Detection Set includes the following primer and probe sets:

- **Inf A/M2:** detects a well-conserved region of the Matrix Protein 2 (M2) gene from influenza A viruses in both seasonal human influenza A virus and 2009 H1N1 virus.

- **Inf A/H1:** detects the presence of the hemagglutinin (HA) gene specifically found in the 2009 H1N1 virus.
  Detection with Inf A/M2 and Inf A/H1 systems are carried out in separate reactions.

- **Internal Control:** detects the human Myostatin gene as a common nucleic acid in patient samples and verifies adequacy of sample and reaction. The primers and probes for Inf A/M2 and Internal Control are combined by the user and the reactions are performed in the same capillary.

The Roche RealTime ready Influenza A/H1N1 Detection Set also includes the following control materials:

- **External Positive Control for Inf A/M2** consists of lyophilized plasmid DNA containing the cloned target sequence of the M2 gene. The Inf A/M2 Positive Control is incorporated into each batch of patient specimen testing for the Inf A/M2 target.
- **External Positive Control for Inf A/H1** consists of lyophilized plasmid DNA containing the cloned target sequence of the hemagglutinin gene of the 2009 H1N1 virus. The Inf A/H1 Positive Control is incorporated into each batch of patient specimen testing for the Inf A/H1 target.
- **Negative Control** consists of nuclease free water and is taken through both nucleic acid extraction and PCR processes to demonstrate that no carryover contamination has occurred during the test process. The Negative Control is incorporated into each batch of patient specimen processing.

The Roche RealTime ready Influenza A/H1N1 Detection Set requires the following hardware with corresponding software:

- MagNA Pure LC 1.0 Instrument or
- MagNA Pure LC 2.0 Instrument
- LightCycler® 2.0 Instrument
- LightCycler® Software Version 4
- LightCycler® Capillaries (20 ml)
- LightCycler® Centrifuge Adapters
- LightCycler® Capping Tool

Optional hardware:

- LC Carousel Centrifuge 2.0 including rotor buckets or
- LC Carousel Centrifuge and LC Carousel Centrifuge 2.0 Rotor Set

The Roche RealTime ready Influenza A/H1N1 Detection Set requires the use of the following additional reagents/materials:

- MagNA Pure LC Total Nucleic Acid Isolation Kit - High Performance
- RealTime ready RNA Virus Master

The above described Roche RealTime ready Influenza A/H1N1 Detection Set, when labeled consistently with the labeling authorized by FDA, entitled RealTime ready Influenza A/H1N1 Detection Set Package Insert, (see *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to CLIA High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Roche RealTime ready Influenza A/H1N1 Detection Set is authorized to be accompanied by the following information pertaining to the emergency use, which are authorized to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Interpreting the Roche RealTime ready Influenza A/H1N1 Detection Set Test Results
- Fact Sheet for Patients: Understanding the Roche RealTime ready Influenza A/H1N1 Detection Set Test Results

As described in section IV below, Roche Diagnostics GmbH, is also authorized to make available additional information relating to the emergency use of the authorized Roche RealTime ready Influenza A/H1N1 Detection Set that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Roche RealTime ready Influenza A/H1N1 Detection Set in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Roche RealTime ready Influenza A/H1N1 Detection Set may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized Roche RealTime ready Influenza A/H1N1 Detection Set, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Roche RealTime ready Influenza A/H1N1 Detection Set under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS' determination under section 564(b)(1)(C) described above and the Secretary of HHS' corresponding declaration under section 564(b)(1), the Roche RealTime ready Influenza A/H1N1 Detection Set described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Roche RealTime ready Influenza A/H1N1 Detection Set during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Roche RealTime ready Influenza A/H1N1 Detection Set.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Roche Diagnostics GmbH

A. Roche Diagnostics GmbH will distribute the authorized Roche RealTime ready Influenza A/H1N1 Detection Set with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. Roche Diagnostics GmbH will provide to the CLIA High Complexity Laboratories the authorized Roche RealTime ready Influenza A/H1N1 Detection Set Fact Sheets for Healthcare Providers and the authorized Roche RealTime ready Influenza A/H1N1 Detection Set Fact Sheets for Patients.

C. Roche Diagnostics GmbH will make available on its website the authorized Roche RealTime ready Influenza A/H1N1 Detection Set Fact Sheets for Healthcare Providers and the authorized Roche RealTime ready Influenza A/H1N1 Detection Set Fact Sheets for Patients.

D. Roche Diagnostics GmbH will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized Roche RealTime ready Influenza A/H1N1 Detection Set shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the authorized Roche RealTime ready Influenza A/H1N1 Detection Set shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;

- This test has been authorized by FDA under an Emergency Use Authorization;

- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;

- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. §360bbb-3(b)(1); and

- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the authorized Roche RealTime ready Influenza A/H1N1 Detection Set may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. Roche Diagnostics GmbH will ensure that CLIA High Complexity Laboratories using the authorized Roche RealTime ready Influenza A/H1N1 Detection Set have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. Roche Diagnostics GmbH will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, Roche Diagnostics GmbH will maintain records of device usage.

K. Roche Diagnostics GmbH will collect information on the performance of the assay and report to FDA any suspected occurrence of false positive or negative results of which Roche Diagnostics GmbH becomes aware.

CLIA High Complexity Laboratories

L. CLIA High Complexity Laboratories will include with reports of the results of the Roche RealTime ready Influenza A/H1N1 Detection Set the authorized Fact Sheets for Healthcare Providers and the authorized Fact Sheets for Patients.

M. CLIA High Complexity Laboratories will use the MagNA Pure LC Instrument and the MagNA Pure LC Total Nucleic Acid Isolation Kit - High Performance for nucleic acid extraction and perform the assay on the LightCycler® V2.0 instrument.

N. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate

O. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to Roche Diagnostics GmbH any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

Roche Diagnostics GmbH and CLIA High Complexity Laboratories

P. Roche Diagnostics GmbH is authorized to make available additional information relating to the emergency use of the authorized Roche RealTime ready Influenza A/H1N1 Detection Set that is consistent with, and does not exceed, the terms of this letter of authorization.

Q. Only Roche Diagnostics GmbH may request changes to the authorized Roche RealTime ready Influenza A/H1N1 Detection Set Fact Sheet for Healthcare Providers or the authorized Roche RealTime ready Influenza A/H1N1 Detection Set Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

R. Roche Diagnostics GmbH will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized Roche RealTime ready Influenza A/H1N1 Detection Set as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(8) The Authorization for the GeneSTAT 2009 A/H1N1 Influenza Test issued on December 9, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Mark J. Rosenfeld, M.S., Ph.D.
Chief Science Advisor, DxNA, LLC
3879 S. River Road, Bldg. A
St. George, UT 84790

Dear Dr. Rosenfeld:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the GeneSTAT 2009 A/H1N1 Influenza Test for the diagnosis of 2009 H1N1 influenza virus infection in patients with signs and symptoms of respiratory infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), by CLIA High Complexity Laboratories, which are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a, to perform high complexity tests.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. §247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. §360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. §360bbb-3(c)) are met, I am authorizing the emergency use of the GeneSTAT 2009 A/H1N1 Influenza Test (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the GeneSTAT 2009 A/H1N1 Influenza Test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the GeneSTAT 2009 A/H1N1 Influenza Test may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the GeneSTAT 2009 A/H1N1 Influenza Test, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the GeneSTAT 2009 A/H1N1 Influenza Test for the diagnosis of 2009 H1N1 influenza virus infection.[2]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized GeneSTAT 2009 A/H1N1 Influenza Test for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized GeneSTAT 2009 A/H1N1 Influenza Test:

The GeneSTAT 2009 A/H1N1 Influenza Test is a reverse-transcription polymerase chain reaction assay for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in nasopharyngeal swabs or nasal swabs from patients with signs and symptoms of respiratory infection. The GeneSTAT 2009 A/H1N1 Influenza Test is to be used in combination with the Roche High Pure RNA Isolation Kit and the GeneSTAT Analytical Platform. The assay is composed of two principal steps: (1) extraction of RNA from patient specimens, (2) one-step reverse transcription and PCR amplification using fluorogenic probes for detection.

The GeneSTAT 2009 A/H1N1 Influenza Test includes the following primer and probe sets:

- **H1:** a primer-probe set designed to detect the presence of the hemagglutinin gene specifically found in the 2009 H1N1 influenza A virus.
- **N1:** a primer-probe set designed to detect the presence of the neuraminidase gene specifically found in the 2009 H1N1 influenza A virus.
- **MA:** a primer-probe set designed to detect the presence of a well conserved region of the matrix gene found in both, seasonal human influenza A virus and 2009 H1N1 influenza A virus.
- **P28:** a primer-probe set designed to detect the presence of the Caprine Arthritis-Encephalitis Virus core polypeptide p28 gene (Exogenous Reaction Control).

The GeneSTAT 2009 A/H1N1 Influenza Test also includes the following control materials:

- **Influenza A Matrix-Positive Control Swab**.
- **H1-Positive Control Swab (2009 H1N1 specific)**.

The GeneSTAT 2009 A/H1N1 Influenza Test requires the following hardware with corresponding software:

- GeneSTAT Analytical Platform.

The GeneSTAT 2009 A/H1N1 Influenza Test requires the use of the following additional reagents/materials:

- GeneSTAT H1N1 Test Module.
- GeneSTAT Sample Prep Vial.
- Roche High Pure RNA Isolation Kit.

The above described GeneSTAT 2009 A/H1N1 Influenza Test, when labeled consistently with the labeling authorized by FDA, entitled GeneSTAT™ 2009 A/H1N1 Influenza Test Package Insert, (see *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to CLIA High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described GeneSTAT 2009 A/H1N1 Influenza Test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet for Healthcare Providers: Interpreting GeneSTAT 2009 A/H1N1 Influenza Test Results**

- **Fact Sheet for Patients: Understanding the GeneSTAT 2009 A/H1N1 Influenza Test Results**

As described in section IV below, DxNA, LLC, is also authorized to make available additional information relating to the emergency use of the authorized GeneSTAT 2009 A/H1N1 Influenza Test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized GeneSTAT 2009 A/H1N1 Influenza Test in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized GeneSTAT 2009 A/H1N1 Influenza Test may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized GeneSTAT 2009 A/H1N1 Influenza Test, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized GeneSTAT 2009 A/H1N1 Influenza Test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS' determination under section 564(b)(1)(C) described above and the Secretary of HHS' corresponding declaration under section 564(b)(1), the GeneSTAT 2009 A/H1N1 Influenza Test described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the GeneSTAT 2009 A/H1N1 Influenza Test during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the GeneSTAT 2009 A/H1N1 Influenza Test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

DxNA, LLC

A. DxNA, LLC will distribute the authorized GeneSTAT 2009 A/H1N1 Influenza Test with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. DxNA, LLC will provide to the CLIA High Complexity Laboratories the authorized GeneSTAT 2009 A/H1N1 Influenza Test Fact Sheets for Healthcare Providers and the authorized GeneSTAT 2009 A/H1N1 Influenza Test Fact Sheets for Patients.

C. DxNA, LLC will make available on its website the authorized GeneSTAT 2009 A/H1N1 Influenza Test Fact Sheets for Healthcare Providers and the authorized GeneSTAT 2009 A/H1N1 Influenza Test Fact Sheets for Patients.

D. DxNA, LLC will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized GeneSTAT 2009 A/H1N1 Influenza Test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the authorized GeneSTAT 2009 A/H1N1 Influenza Test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;

- This test has been authorized by FDA under an Emergency Use Authorization;

- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;

- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. §360bbb-3(b)(1); and

- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the authorized GeneSTAT 2009 A/H1N1 Influenza Test may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. DxNA, LLC will ensure that CLIA High Complexity Laboratories using the authorized GeneSTAT 2009 A/H1N1 Influenza Test have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. DxNA, LLC will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, DxNA, LLC will maintain records of device usage.

K. DxNA, LLC will collect information on the performance of the assay and report to FDA any suspected occurrence of false positive or negative results of which DxNA, LLC becomes aware.

CLIA High Complexity Laboratories

L. CLIA High Complexity Laboratories will include with reports of the results of the GeneSTAT 2009 A/H1N1 Influenza Test the authorized Fact Sheets for Healthcare Providers and the authorized Fact Sheets for Patients.

M. CLIA High Complexity Laboratories will use the Roche High Pure RNA Isolation Kit for nucleic acid extraction and perform the assay on the GeneSTAT Analytical Platform, ensuring that at least once per day that specimens are to be tested, a known sample (2009 H1N1 positive or influenza A positive specimen) is tested as a positive control for RNA extraction and subsequent protocol steps.

N. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

O. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to DxNA, LLC any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

DxNA, LLC and CLIA High Complexity Laboratories

P. DxNA, LLC is authorized to make available additional information relating to the emergency use of the authorized GeneSTAT 2009 A/H1N1 Influenza Test that is consistent with, and does not exceed, the terms of this letter of authorization.

Q. Only DxNA, LLC may request changes to the authorized GeneSTAT 2009 A/H1N1 Influenza Test Fact Sheet for Healthcare Providers or the authorized GeneSTAT 2009 A/H1N1 Influenza Test Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

R. DxNA, LLC will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized GeneSTAT 2009 A/H1N1 Influenza Test as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(9) The Authorization for the TessArray Resequencing Influenza A Microarray Detection Panel issued on December 16, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Clark Tibbetts, PhD
Executive Vice President
TessArae, LLC
46090 Lake Center Plaza
Suite 304
Sterling, VA 20165

Dear Dr. Tibbetts:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for emergency use of the TessArray® Resequencing Influenza A Microarray Detection Panel (TessArray RM-Flu) for the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results, in patients with signs and symptoms of respiratory infection, by CLIA High Complexity Laboratories, which are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a, to perform high complexity tests.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. §247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[1] Pursuant to section 564(b) of the Act (21 U.S.C. §360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. §360bbb-3(c)) are met, I am authorizing the emergency use of the TessArray RM-Flu (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results, in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the TessArray RM-Flu for the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results, in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus.

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the TessArray RM-Flu may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the TessArray RM-Flu, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the TessArray RM-Flu for the diagnosis of 2009 H1N1 influenza virus infection.[2]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized TessArray RM-Flu for the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results, in individuals with signs and symptoms of respiratory infection.

The Authorized TessArray RM-Flu:

The TessArray RM-Flu is a resequencing microarray assay for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in throat swabs from patients with signs and symptoms of respiratory infection. The TessArray RM-Flu is to be used in combination with the EPICENTRE Masterpure™ Complete DNA and RNA Purification Kit and the Affymetrix® GeneChip® Microarray Instrumentation System. The assay protocol follows a number of steps, starting from RNA extraction from patient specimens, through reverse transcription and amplification by multiplex PCR, followed by labeling of fragmented DNA and hybridization to a microarray. After washing, the array is stained with fluorescent dye and subsequently scanned. The image analysis readout sequence from the detector tiles in the array is scored and also submitted for BLAST homology determination, to define the most similar homology with any known flu virus sequence.

The gene resequencing detector tiles of the TessArray RM-Flu assay represent:

- *2009 H1N1 influenza virus*
  - **NA1av** an avian type A influenza virus neuraminidase gene sequence
  - **NSav** an avian type A influenza virus non-structural gene sequence
  - **M1hu** a representative matrix gene sequence from seasonal A/H1N1
  - **M3hu** a representative matrix gene sequence from seasonal A/H3N2
  - **M5Av** an avian type A influenza virus matrix gene sequence
- *Seasonal A/H1N1*
  - **HA1hu** a representative hemagglutinin gene sequence from A/H1N
  - **NA1hu** a representative neuraminidase gene sequence from A/H1N1
  - **M1hu** a representative matrix gene sequence from seasonal A/H1N1
  - **M3hu** a representative matrix gene sequence from seasonal A/H3N2
  - **M5Av** an avian type A influenza virus matrix gene sequence
- *Seasonal A/H3N2*
  - **HA3hu** a representative hemagglutinin gene sequence from A/H1N1
  - **NA2hu** a representative neuraminidase gene sequence from A/H1N1
  - **M1hu** a representative matrix gene sequence from seasonal A/H1N1
  - **M3hu** a representative matrix gene sequence from seasonal A/H3N2
  - **M5Av** an avian type A influenza virus matrix gene sequence

The TessArray RM-Flu assay also includes the following control detector tiles:

Negative/Background Controls: 25 non-analyte resequencing detector tiles as background control detector tiles representing a variety of different type A influenza virus HA and NA genes, from subtypes that rarely infect humans. They are used to set a threshold for detection of the assay's targeted influenza viruses and to monitor resequencing data quality of the assay.

Positive/Protocol Controls: Each batch of specimens to be tested should include a known sample, such as that of a seasonal influenza virus vaccine, as a positive control for RNA extraction and subsequent protocol steps. Two additional resequencing detector tiles represent over 1,000 nucleotides of sequences of the TIM and NAC1 genes from *Arabidopsis thaliana* (wild mustard weed). Template controls are included in each specimen. Positive scoring of these controls provides assurance of successful execution of the different steps in the sample processing.

The TessArray RM-Flu assay requires the following hardware with corresponding software:

- **Thermal Cyclers** that were tested with the RM-Flu Multiplex PCR:
  - Bio-Rad MJ Mini
  - Bio-Rad MyCycler
  - Bio-Rad Peltier DNA Engine Tetrad
- **Affymetrix® GeneChip® Microarray Instrumentation Systems** tested:
  - GCS 3000 7G (RUO)
  - GCS 3000Dx (IVD)
  - GCS 3000Dx2 (IVD)
- **Workstation and Software**:
  - GCOS/GSEQ
  - AGCC/GSEQ
  - AGCC-Dx or AGCC-Dx2

The TessArray RM-Flu assay requires the use of the following additional reagents/materials:

- EPICENTRE® Biotechnologies Masterpure™ Complete DNA and RNA Purification Kit
- Life Technologies™ Superscript™ III Reverse Transcriptase
- Life Technologies™ RNaseOUT™ Recombinant Ribonuclease Inhibitor
- Promega®, GoTaq® Flexi DNA Polymerase
- USB (Affymetrix®) Uracil-DNA Glycosylase (UDG), Heat-Labile
- Qiagen® QIAquick® PCR Purification Kit
- Affymetrix® GeneChip® Resequencing Assay Kit

The above described TessArray RM-Flu test, when labeled consistently with the labeling authorized by FDA, entitled TessArray RM-Flu Package Insert, (available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by CLIA High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described TessArray RM-Flu is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet for Healthcare Providers: Interpreting TessArray® Resequencing Influenza A Microarray Detection Panel (TessArray RM-Flu) Test Results**

- **Fact Sheet for Patients: Understanding the TessArray® Resequencing Influenza A Microarray Detection Panel (TessArray RM-Flu) Test Results**

As described in section IV below, TessArae, LLC, is also authorized to make available additional information relating to the emergency use of the authorized TessArray RM-Flu that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized TessArray RM-Flu in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized TessArray RM-Flu may be effective in the diagnosis of 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results, pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized TessArray RM-Flu, when used to diagnose 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized TessArray RM-Flu under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the TessArray RM-Flu described above is authorized to diagnose 2009 H1N1 influenza virus infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results, in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the TessArray RM-Flu during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the TessArray RM-Flu.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

TessArae, LLC

A. TessArae, LLC will distribute the authorized TessArray RM-Flu with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories.

B. TessArae, LLC will provide to the CLIA High Complexity Laboratories the authorized TessArray RM-Flu Fact Sheet for Healthcare Providers and the authorized TessArray RM-Flu Fact Sheet for Patients.

C. TessArae, LLC will make available on its website the authorized TessArray RM-Flu Fact Sheet for Healthcare Providers and the authorized TessArray RM-Flu Fact Sheet for Patients.

D. TessArae, LLC will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized TessArray RM-Flu shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the authorized TessArray RM-Flu shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. §360bbb-3(b)(1); and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the authorized TessArray RM-Flu may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. TessArae, LLC will ensure that CLIA High Complexity Laboratories using the authorized TessArray RM-Flu have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. TessArae, LLC will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, TessArae, LLC will maintain records of device usage.

K. TessArae, LLC will collect information on the performance of the assay and report to FDA any suspected occurrence of false positive or false negative results of which TessArae, LLC becomes aware.

L. TessArae, LLC is authorized to make available additional information relating to the emergency use of the authorized TessArray RM-Flu that is consistent with, and does not exceed, the terms of this letter of authorization.

M. Only TessArae, LLC may request changes to the authorized TessArray RM-Flu Fact Sheet for Healthcare Providers or the authorized TessArray RM-Flu Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

CLIA High Complexity Laboratories

N. CLIA High Complexity Laboratories will include with reports of the results of the TessArray RM-Flu the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

O. CLIA High Complexity Laboratories will use the EPICENTRE Masterpure™ Complete DNA and RNA Purification Kit for nucleic acid extraction and perform the assay on the Affymetrix® GeneChip® Microarray Instrumentation System, ensuring that at least once per day specimens are tested, a known sample (such as that of a seasonal influenza virus vaccine) is tested as a positive control for RNA extraction, and is processed through all subsequent protocol steps.

P. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

Q. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to TessArae, LLC any suspected occurrence of false positive or false negative results of which CLIA High Complexity Laboratories become aware.

R. CLIA High Complexity Laboratories will clearly and conspicuously state on reports of the results of the TessArray RM-Flu that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other pathogen.

TessArae, LLC and CLIA High Complexity Laboratories

S. TessArae, LLC, and CLIA High Complexity Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized TessArray RM-Flu test as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[2] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(10) The Authorization for the CDC Swine Influenza Virus Real-time rRT-PCR Detection Panel issued on April 27, 2009, amended on May 2, 2009, and as amended again and reissued in its entirety on December 18, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Frieden:

On April 27, 2009, FDA issued a letter authorizing the emergency use of the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) assay for the presumptive diagnosis of 2009 H1N1 influenza virus infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by public health and other qualified laboratories. On May 1, 2009, CDC submitted a request for an amendment to the Emergency Use Authorization.[1] On August 31, 2009 CDC submitted a request for a second amendment[2] and on November 30, 2009 CDC submitted a request for a third amendment[3] to the Emergency Use Authorization G090072. In response to those requests, the letter authorizing emergency use of the rRT-PCR Swine Flu Panel is being reissued in its entirety with the amendments, as requested by CDC.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents -- in this case, 2009 H1N1 influenza virus.[4] Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the rRT-PCR Swine Flu Panel for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the rRT-PCR Swine Flu Panel may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the rRT-PCR Swine Flu Panel, when used in the diagnosis of 2009 H1N1influenza virus infection, outweigh the known and potential risks of such products; and

3. There is no adequate, approved, and available alternative to the emergency use of the rRT-PCR Swine Flu Panel for the diagnosis of 2009 H1N1 influenza virus infection.[5]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized rRT-PCR Swine Flu Panel for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized rRT-PCR Swine Flu Panel:

The Swine Influenza Virus Real-time RT-PCR Detection Panel is a panel of oligonucleotide primers and dual-labeled hydrolysis (Taqman®) probes for use in the real-time RT-PCR assay on the Roche LightCycler® 2.0, and the Applied Biosystems (ABI) 7500 Fast Dx Real-time PCR, and the RUO marketed 7500 Fast Real-time PCR instruments for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in upper respiratory tract specimens (such as nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), dual NPS/TS swabs, or nasal aspirates (NA)) and the lower respiratory tract specimens (such as bronchoalveolar lavage (BAL), bronchial aspirate (BA); bronchial washes (BW), endotracheal aspirates (EA) and endotracheal wash (EW), tracheal aspirates (TA), and lung tissue) from patients with signs and symptoms of respiratory infection and from viral culture. The universal influenza A (Matrix gene), 2009 H1N1 influenza swInfA (NP gene), and swH1 (HA gene) primer and probe sets are designed for detection of 2009 H1N1 influenza viruses.

The rRT-PCR Swine Flu Panel includes the following primer and probe sets:
- **InfA** detects a well-conserved region of the Matrix Protein (M) gene from influenza A viruses in both seasonal human influenza A virus and 2009 H1N1 virus.
- **swInfA** specifically detects the 2009 H1N1 influenza strains (NP gene).
- **swH1** is specific for the 2009 H1N1 influenza and detects the presence of the hemagglutinin (HA) gene specifically found in the 2009 H1N1 virus.

The rRT-PCR Swine Flu Panel also includes control materials:
- **RNase P (RP)** detects human RNase P and is used as a positive control with human clinical specimens to indicate that adequate isolation of nucleic acid resulted from the extraction of the clinical specimen.
- **Swine Influenza Panel Real-Time RT-PCR Positive Control (SIPC)** is a positive control designed to react with all the primer and probe sets including RNase P.

The above rRT-PCR Swine Flu Panel, when labeled consistently with the labeling authorized by FDA, entitled the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) (see *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to public health and other qualified laboratories[6] under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described rRT-PCR Swine Flu Panel is authorized to be accompanied by the following information pertaining to the emergency use, which are authorized to be made available to health care providers and patients:

- **Fact Sheet For Healthcare Providers: Interpreting the Swine Influenza Virus Real-time RT-PCR Detection Panel Test Results**

- **Fact Sheet For Patients: Understanding rRT-PCR Swine Influenza Detection Panel Test Results**

As described in section IV below, CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Swine Flu Panel that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized rRT-PCR Swine Flu Panel in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized rRT-PCR Swine Flu Panel may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized rRT-PCR Swine Flu Panel, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized rRT-PCR Swine Flu Panel under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS' determination under section 564(b)(1)(C) described above and the Secretary of HHS' corresponding declaration under section 564(b)(1), the rRT-PCR Swine Flu Panel described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the rRT-PCR Swine Flu Panel during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the rRT-PCR Swine Flu Panel;
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12);

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

A. CDC will distribute the rRT-PCR Swine Flu Panel with the authorized labeling, as may be revised with written permission of FDA only to qualified laboratories.

B. CDC will provide to the qualified laboratories and state and/or local public health authority(ies) the authorized rRT-PCR Swine Flu Panel Fact Sheets for Health Care Providers, and the authorized rRT-PCR Swine Flu Panel Fact Sheets for Patients.

C. CDC will make available on its website the authorized rRT-PCR Swine Flu Panel Fact Sheets for Health Care Providers, and the authorized rRT-PCR Swine Flu Panel Fact Sheets for Patients.

D. CDC will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. CDC will ensure that qualified laboratories using the rRT-PCR Swine Flu Panel have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

F. CDC will track adverse events and report to FDA as required under 21 CFR part 803.

G. Through a process of inventory control, CDC will maintain records of device usage.

H. CDC will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive and negative results of which CDC becomes aware.

Public Health and Other Qualified Laboratories

I. Public health and other qualified laboratories will include with reports of the results of the rRT-PCR Swine Flu Panel, the authorized Fact Sheets for Health Care Providers and the authorized Fact Sheet for Patients.

J. Qualified laboratories will perform the assay on the Roche LightCycler® 2.0 Real-time PCR system, or an Applied Biosystems 7500 Fast Dx Real-time PCR instrument, or the RUO marketed Applied Biosystems 7500 Real-time PCR instrument that is validated by Applied Biosystems with regard to the updated software but only partially qualified regarding its laboratory performance (proficiency testing with the CDC sample panel not performed).

K. Qualified laboratories will have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

L. Qualified laboratories will collect information on the performance of the assay, and report to CDC any suspected occurrence of false positive or false negative results of which qualified laboratories become aware.

CDC and State and/or Local Public Health Authority(ies)

M. CDC and the appropriate state and/or local public health authority(ies) are authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Swine Flu Panel that is consistent with, and does not exceed, the terms of this letter of authorization.

N. Only CDC may request changes to the authorized Fact Sheet for Health Care Providers or the authorized rRT-PCR Swine Flu Panel Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

O. CDC and the appropriate state/and or local public health authority(ies) will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized rRT-PCR Swine Flu Panel as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

[1] The amendment to the April 27, 2009 letter allow use of different sample types (throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens) and different reagents.
[2] The amendment to the May 2, 2009 letter allow use of the LightCycler® 2.0 Real-time PCR system, in addition to the ABI 7500 Fast Dx system, with the CDC rRT-PCR Swine Flu Panel .
[3] The amendment to the May 2, 2009 letter authorize use of nasal washes as additional upper respiratory tract specimen and use of lower respiratory tract specimens (such as bronchoalveolar lavage (BAL), bronchial aspirate (BA); bronchial wash (BW); endotracheal aspirate (EA); endotracheal wash (EW); tracheal aspirate (TA), and lung tissue) as acceptable clinical specimens with the CDC rRT-PCR Swine Flu Panel; to remove the word "presumptive" from the Intended Use; to allow the use of the CDC rRT-PCR Swine Flu Panel as a stand alone test; to include Human Specimen Control (HSC) that was previously included in the CDC rRT-PCR Flu Panel (IVD, K080570); and to update packaging by removing product from foam envelopes and segregating into boxes. There are also minor wording changes made to be consistent with more recently issued Emergency Use Authorizations for in vitro diagnostic devices.
[4] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[4] All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by a CDC instructor or designee prior to use. CDC Influenza Division will limit the distribution of this device to those users who have successfully completed training provided by CDC instructors or designees. Use is limited to designated laboratories that are qualified to receive and use the CDC rRT-PCR Flu Panel (IVD) 510(K) 080570. See "Conditions of Authorization" below.

(11) The Authorization for the Cepheid Xpert Flu A Panel issued on December 24, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Russel K. Enns, Ph.D.
Senior Vice President
Regulatory, Clinical & Government Affairs and Quality Systems
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

Dear Dr. Enns:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Cepheid Xpert® Flu A Panel for the diagnosis of 2009 H1N1 influenza virus infection in patients with signs and symptoms of respiratory infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity tests and by laboratories certified under CLIA to perform high complexity tests.[1]

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. §247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents - in this case, 2009 H1N1 influenza virus.[2] Pursuant to section 564(b) of the Act (21 U.S.C. §360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for the detection of 2009 H1N1 influenza virus, subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. §360bbb-3(c)) are met, I am authorizing the emergency use of the Xpert® Flu A Panel (as described in the scope section of this letter (Section II)) for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Xpert® Flu A Panel for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The 2009 H1N1 influenza virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Xpert® Flu A Panel may be effective for the diagnosis of 2009 H1N1 influenza virus infection, and that the known and potential benefits of the Xpert® Flu A Panel, when used in the diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Xpert® Flu A Panel for the diagnosis of 2009 H1N1 influenza virus infection.[3]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Xpert® Flu A Panel for the diagnosis of 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

The Authorized Xpert® Flu A Panel:

The Cepheid Xpert Flu A Panel is a rapid, automated *in vitro* diagnostic test for qualitative detection and differentiation of 2009 H1N1 influenza virus RNA. The assay is performed on the Cepheid GeneXpert Dx System. The system automates and integrates sample purification, nucleic acid amplification, and detection of the target viral RNA sequences using real-time reverse transcriptase polymerase chain reaction (rRT-PCR). The system consists of an instrument, personal computer, and preloaded software for running tests and viewing the results.

The assay detects specific viral gene sequences for the Flu A matrix (Flu A target), and the hemagglutinin gene of 2009 H1N1 influenza virus (2009 H1N1 target). The specimen types for which analytical and method comparison in clinical samples performance data are provided include nasal aspirates/washes (NA/W) and nasopharyngeal (NP) swab specimens in viral transport media (VTM) or universal transport media (UTM) collected from patients suspected of having influenza.

Components of the Test:
The Xpert Flu A Panel includes the following assays:

- Flu A Matrix: four forward primer sequences, three reverse primers and one probe sequence for detecting the matrix gene in Flu A
- 2009 H1: two forward primer sequences, one reverse primer and one probe sequence for detecting the hemagglutinin gene in 2009 Flu A H1.

The Xpert Flu A Panel also includes the following controls:

- SPC: Armored RNA in the form of a dry bead that is included in each cartridge to verify adequate processing of the sample virus.
- PCC: The Probe Check Control PCC indicates that the probes and dyes are present and intact

The Xpert Flu A Panel requires the following hardware with corresponding software:

- Cepheid GeneXpert Dx System and software package

The above described Xpert Flu A Panel , when labeled consistently with the labeling authorized by FDA, entitled Xpert Flu A Panel Assay Package Insert, (available at *http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm*), as may be revised with written permission of FDA, is authorized to be distributed to and used by CLIA Moderate and High Complexity Laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Xpert® Flu A Panel is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- **Fact Sheet For Healthcare Providers: Interpreting Cepheid® Xpert® Flu A Panel Test Results**

- **Fact Sheet For Patients: Understanding Cepheid® Xpert® Flu A Panel Test Results**

As described in section IV below, Cepheid is also authorized to make available additional information relating to the emergency use of the authorized Xpert® Flu A Panel that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Xpert® Flu A Panel in the specified population, when used for diagnosis of 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Xpert® Flu A Panel may be effective in the diagnosis of 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized Xpert® Flu A Panel, when used to diagnose 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Xpert® Flu A Panel under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Xpert® Flu A Panel described above is authorized to diagnose 2009 H1N1 influenza virus infection in individuals with signs and symptoms of respiratory infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Xpert® Flu A Panel during the duration of this emergency use authorization:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Xpert® Flu A Panel.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Cepheid

A. Cepheid will distribute the authorized Xpert® Flu A Panel with the authorized labeling, as may be revised with written permission of FDA, only to CLIA Moderate and High Complexity Laboratories.

B. Cepheid will provide to the CLIA Moderate and High Complexity Laboratories the authorized Xpert® Flu A Panel Fact Sheet for Healthcare Providers and the authorized Xpert® Flu A Panel Fact Sheet for Patients.

C. Cepheid will make available on its website the authorized Xpert® Flu A Panel Fact Sheet for Healthcare Providers and the authorized Xpert® Flu A Panel Fact Sheet for Patients.

D. Cepheid will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.

E. All advertising and promotional descriptive printed matter relating to the use of the authorized Xpert® Flu A Panel shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

F. All advertising and promotional descriptive printed matter relating to the use of the authorized Xpert® Flu A Panel shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- FDA has not determined that this test may be performed in settings with certificates of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a;
- This test has been authorized by FDA under an Emergency Use Authorization;
- This test has been authorized only for the detection of 2009 H1N1 influenza virus and not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is revoked sooner; and
- The declaration of emergency will expire on April 26, 2010, unless it is terminated sooner or renewed.

G. No advertising or promotional descriptive printed matter relating to the use of the authorized Xpert® Flu A Panel may represent or suggest that this test is safe or effective for the diagnosis of 2009 H1N1 influenza virus.

H. Cepheid will ensure that CLIA Moderate and High Complexity Laboratories using the authorized Xpert® Flu A Panel have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

I. Cepheid will track adverse events and report to FDA as required under 21 CFR part 803.

J. Through a process of inventory control, Cepheid will maintain records of device usage.

K. Cepheid will collect information on the performance of the assay and report to FDA any suspected occurrence of false positive or false negative results of which Cepheid becomes aware.

L. Cepheid is authorized to make available additional information relating to the emergency use of the authorized Xpert® Flu A Panel that is consistent with, and does not exceed, the terms of this letter of authorization.

M. Only Cepheid may request changes to the authorized Xpert® Flu A Panel Fact Sheet for Healthcare Providers or the authorized Xpert® Flu A Panel Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

CLIA Moderate and High Complexity Laboratories

N. CLIA Moderate and High Complexity Laboratories will include with reports of the results of the Xpert® Flu A Panel the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.

O. CLIA Moderate and High Complexity Laboratories will perform the assay on the Cepheid GeneXpert Dx System.

P. CLIA Moderate and High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state and/or local public health authorities, as appropriate.

Q. CLIA Moderate and High Complexity Laboratories will collect information on the performance of the assay, and report to Cepheid any suspected occurrence of false positive or false negative results of which CLIA Moderate and High Complexity Laboratories become aware.

R. CLIA Moderate and High Complexity Laboratories will clearly and conspicuously state on reports of the results of the Xpert Flu A that this test is only authorized for the diagnosis of 2009 H1N1 influenza virus and not for seasonal influenza A, B, or any other pathogen.

Cepheid and CLIA Moderate and High Complexity Laboratories

S. Cepheid and CLIA Moderate and High Complexity Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized Xpert® Flu A Panel as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner of Food and Drugs

[1] For ease of reference this letter will refer to these two types of laboratories together as "CLIA Moderate and High Complexity Laboratories."
[2] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[3] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

Dated: April 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8605 Filed 4–16–10; 8:45 am]

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Federal Register

Monday,
April 19, 2010

Part III

Department of Commerce

National Oceanic and Atmospheric Administration

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to an Exploration Drilling Program Near Camden Bay, Beaufort Sea, Alaska; Notice

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XU80

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to an Exploration Drilling Program Near Camden Bay, Beaufort Sea, AK

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

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS received an application from Shell Offshore Inc. (Shell) for an Incidental Harassment Authorization (IHA) to take marine mammals, by harassment, incidental to offshore exploration drilling on Outer Continental Shelf (OCS) leases in the Beaufort Sea, Alaska. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to Shell to take, by Level B harassment only, six species of marine mammals during the specified activity.

DATES: Comments and information must be received no later than May 19, 2010.

ADDRESSES: Comments on the application should be addressed to Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for providing email comments is *PR1.0648–XU80@noaa.gov*. NMFS is not responsible for e-mail comments sent to addresses other than the one provided here. Comments sent via e-mail, including all attachments, must not exceed a 10-megabyte file size.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm* 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.

A copy of the application used in this document may be obtained by writing to the address specified above, telephoning the contact listed below (*see* **FOR FURTHER INFORMATION CONTACT**), or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm*. The following associated documents are also available at the same internet address: Shell's 2010 Exploration Drilling Communication Plan Beaufort Sea, Alaska, and Shell's 2010 Plan of Cooperation (POC) Camden Bay, Alaska. Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Candace Nachman, Office of Protected Resources, NMFS, (301) 713–2289, ext 156.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined "negligible impact" in 50 CFR 216.103 as "* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization.

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as:

> Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild ["Level A harassment"]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering ["Level B harassment"].

Summary of Request

NMFS received an application on May 11, 2009, from Shell for the taking, by harassment, of marine mammals incidental to offshore exploration drilling on OCS leases in the Beaufort Sea, Alaska. NMFS reviewed Shell's application and identified a number of issues requiring further clarification. After addressing comments from NMFS, Shell modified its application and submitted a revised application on December 10, 2009. However, after some additional discussions regarding certain activities, NMFS determined that a second revision to the application was warranted. The latest revised application was submitted to NMFS on March 18, 2010. NMFS carefully evaluated Shell's application, including their analyses, and determined that the application is complete and that it is appropriate to make the necessary preliminary determinations pursuant to the MMPA. The March 18, 2010, application is the one available for public comment (*see* **ADDRESSES**) and considered by NMFS for this proposed IHA.

Shell intends to drill two exploration wells at the Torpedo and Sivulliq prospects in Camden Bay, Beaufort Sea, Alaska, during the 2010 Arctic open-water season (July through October). Impacts to marine mammals may occur from noise produced by the drillship and supporting vessels and aircraft. Shell has requested an authorization to take 11 marine mammal species by Level B harassment. However, some of these species are not expected to be found in the activity area. Therefore, NMFS is proposing to authorize take of six marine mammal species, by Level B harassment, incidental to Shell's offshore exploration drilling in Camden Bay. These species include: beluga whale (*Delphinapterus leucas*); bowhead whale (*Balaena mysticetus*); gray whale (*Eschrichtius robustus*); bearded seal (*Erignathus barbatus*); ringed seal (*Phoca hispida*); and spotted seal (*P. largha*).

Description of the Specified Activity

Shell plans to conduct an offshore exploration drilling program on U.S. Department of the Interior, Minerals Management Service (MMS) Alaska OCS leases located north of Point Thomson near Camden Bay in the Beaufort Sea, Alaska, during the 2010 open-water season. During the 2010 drilling program, Shell plans to complete two exploration wells at two drill sites, one well each on the Torpedo (NR06–04 Flaxman Island lease block 6610, OCS–Y–1941 [Flaxman Island 6610]) and Sivulliq prospects (NR06–04 Flaxman Island lease block 6658, OCS–Y 1805 [Flaxman Island 6658]). *See* Figure 1–1 in Shell's application for the lease block and drill site locations *(see* **ADDRESSES**). All drilling is planned to be vertical.

Shell plans to drill the Torpedo prospect well first, followed by the Sivulliq well, unless adverse surface conditions or other factors dictate a reversal of drilling sequence. In that case, Shell will mobilize to the Sivulliq prospect and drill there first. The Torpedo H drill site is located 22 mi (35.4 km) from shore in water 120 ft (36.6 m) deep. The Sivulliq N drill site is located 16 mi (25.7 km) from shore with a water depth of 107 ft (32.6 m).

The ice reinforced drillship *Discoverer* will be used to drill the wells. The *Discoverer* is 514 ft (156.7 m) long with a maximum height (above keel) of 274 ft (83.7 m). Additional rig specifications for the *Discoverer* can be found in Attachment A of Shell's application (*see* **ADDRESSES**). While on location at the drill sites, the *Discoverer* will be affixed to the seafloor using eight 7-ton Stevpris anchors arranged in a radial array.

During the 2010 drilling season, the *Discoverer* will be attended by a minimum of seven vessels that will be used for ice-management, anchor handling, oil spill response (OSR), refueling, resupply, and servicing of the drilling operations. The ice-management vessels will consist of an icebreaker and an anchor handler. Table 1–1 in Shell's application provides a list of the support vessels that will be used during the drilling program, as well as information about trip frequency and duration for each vessel.

Re-supply between the drill sites and West Dock will use a coastwide qualified vessel. An ice-capable OSR barge (OSRB), with an associated tug, will be located nearby during the planned drilling program. The OSRB will be supported by a berthing vessel for the OSR crew. An OSR tanker also will be nearby for its storage capability of recovered liquids.

Shell's base plan is for two ice-management/anchor handling vessels, the M/V *Vladimir Ignatjuk* and the ice-management/anchor handling vessel *M/V Nordica* or similar vessels, to accompany the *Discoverer* traveling north of Dutch Harbor through the Bering Strait, after July 1, 2010, then through the Chukchi Sea, around Pt. Barrow, and east through the Alaskan Beaufort Sea, before arriving on location at the Torpedo "H" location on or about July 10, or Sivulliq "N" if adverse surface conditions or other factors dictate a reversal of drilling sequence. At the completion of the drilling season on or before October 31, 2010, one or two ice-management vessels, along with various support vessels, such as the OSR fleet, will accompany the *Discoverer* as it travels west through the Beaufort Sea, then south through the Chukchi Sea and the Bering Strait. Subject to ice conditions, alternate exit routes may be considered. Shell has planned a suspension of all operations beginning on August 25 for the Nuiqsut (Cross Island) and Kaktovik subsistence bowhead whale hunts. The *Discoverer* and support vessels will leave the Camden Bay project area, will move to a location at or north of 71.25°N. latitude and at or west of 146.4°W. longitude and will return to resume activities after the Nuiqsut (Cross Island) and Kaktovik subsistence bowhead whale hunts conclude.

Shell will cease drilling on or before October 31, after which the *Discoverer* will exit the Alaskan Beaufort Sea. In total, Shell anticipates that the exploration drilling program will require approximately 74 drilling days, excluding weather delays, the shutdown period to accommodate the fall bowhead whale harvests at Kaktovik and Cross Island (Nuiqsut), or other operational delays. Shell assumes approximately 11 additional days will be needed for drillship mobilization, drillship moves between locations, and drillship demobilization.

Activities associated with the 2010 Beaufort Sea exploration drilling program include operation of the *Discoverer,* associated support vessels, crew change support and re-supply. The *Discoverer* will remain at the location of the designated exploration drill sites except when mobilizing and demobilizing to and from Camden Bay, transiting between drill sites, and temporarily moving off location if it is determined ice conditions require such a move to ensure the safety of personnel and/or the environment in accordance with Shell's Ice-management Plan (IMP). Ice-management vessels, anchor tenders, and OSR vessels will remain in close proximity to the drillship during drilling operations.

Shell recognizes that the drilling program is located in an area that is characterized by active sea ice movement, ice scouring, and storm surges. In anticipation of potential ice hazards that may be encountered, Shell has developed and will implement an IMP to ensure real-time ice and weather forecasting is conducted in order to identify conditions that might put operations at risk and will modify its activities accordingly. The IMP also contains ice threat classification levels depending on the time available to suspend drilling operations, secure the well, and escape from advancing hazardous ice. Real-time ice and weather forecasting will be available to operations personnel for planning purposes and to alert the fleet of impending hazardous ice and weather conditions. Ice and weather forecasting is provided by Shell's Ice and Weather Advisory Center. The center is continuously manned by experienced personnel, who rely on a number of data sources for ice forecasting and tracking, including:

- Radarsat and Envisat data—satellites with Synthetic Aperture Radar, providing all-weather imagery of ice conditions with very high resolution;
- Moderate Resolution Imaging Spectroradiometer—a satellite providing lower resolution visual and near infrared imagery;
- Aerial reconnaissance—provided by specially deployed fixed wing or rotary wing aircraft for confirmation of ice conditions and position;
- Reports from ice specialists on the ice-management and anchor handling vessels and from the ice observer on the drillship;
- Incidental ice data provided by commercial ships transiting the area; and
- Information from NOAA ice centers and the University of Colorado.

The ice-management/anchor handling vessels would manage the ice by deflecting any ice floes that could affect the *Discoverer* when it is drilling and would also handle the *Discoverer's* anchors during connection to and separation from the seafloor. The ice floe frequency and intensity are unpredictable and could range from no ice to ice sufficiently dense that the fleet has insufficient capacity to continue operating, and the *Discoverer* would need to disconnect from its anchors and move off site. If ice is present, ice-management activities may be necessary

in early July and towards the end of operations in late October, but it is not expected to be needed throughout the proposed drilling season. Shell has indicated that when ice is present at the drill site, ice disturbance will be limited to the minimum needed to allow drilling to continue. First-year ice will be the type most likely to be encountered. The ice-management vessels will be tasked with managing the ice so that it will flow easily around and past the *Discoverer* without building up in front of it. This type of ice is managed by the ice-management vessel continually moving back and forth across the drift line, directly up-drift of the *Discoverer* and making turns at both ends. During ice-management, the vessel's propeller is rotating at approximately 15–20 percent of the vessel's propeller rotation capacity. Ice-management occurs with slow movements of the vessel using lower power and therefore slower propeller rotation speed (*i.e.,* lower cavitation), allowing for fewer repositions of the vessel, thereby reducing cavitation effects in the water. Occasionally, there may be multi-year ice ridges that would be managed at a much slower speed than that used to manage first-year ice. Shell has indicated that they do not have any intention of breaking ice with the ice-management vessels but, rather, intend to push it out of the area as described here. Should ice become so prevalent in the drilling area that it is difficult to continue operations without the breaking of ice, Shell has indicated that they would stop operations and move off site instead of breaking ice (S. Childs, Shell, 2010, pers. comm.). Shell has indicated that ice breaking would only be conducted if the ice poses an immediate safety hazard at the drill sites.

Crew change/re-supply vessels will transit to and from the drillship at the estimated frequency shown in Table 1–1 in Shell's application. Helicopters are planned to provide support for crew change, provision re-supply, and search-and-rescue operations during the drilling season. The aircraft operations will principally be based in Deadhorse, Alaska.

Potential impacts to marine mammals could occur from the noise produced by the drillship and its support vessels and aircraft. The drillship produces continuous noise into the marine environment. NMFS currently uses a threshold of 120 dB re 1 μPa (rms) for the onset of Level B harassment from continuous sound sources. Sound measurements from the *Discoverer* have not previously been conducted in the Arctic or elsewhere; however, sounds from a similar drillship, the *Northern Explorer II,* were measured at two different times and locations in the Beaufort Sea (Miles *et al.,* 1987; Greene, 1987a). The underwater received sound pressure level (SPL) in the 20–1,000 Hz band for drilling activity by the *Northern Explorer II,* including a nearby support vessel, was 134 dB re 1 μPa (rms) at 0.1 mi (0.2 km; Greene, 1987b). The back-propagated source levels (175 dB re 1 μPa at 1 m) from these measurements were used as a proxy for modeling the sounds likely to be produced by drilling activities from the *Discoverer.* NMFS has determined that the sound measurements for the *Northern Explorer II* constitute a good proxy for estimating sound radii for the *Discoverer.* Sound propagation measurements will be performed on the *Discoverer* in 2010 once on location near the Camden Bay drill sites in the Beaufort Sea. The results of those measurements will be used during the drilling season to implement proposed mitigation measures described later in this document (see the "Proposed Mitigation" section).

Although there will be several support vessels in the drilling operations area, NMFS considers the possibility of collisions with marine mammals highly unlikely. Once on location, the majority of the support vessels will remain in the area of the drillship throughout the 2010 drilling season and will not be making trips between the shorebase and the offshore vessels. Aircraft travel would be controlled by Federal Aviation Administration approved flight paths. Shell has agreed to a flight altitude of 1,500 ft (457 m; except during takeoffs and landings or during emergencies) for all non-marine mammal monitoring flights to minimize impacts on marine mammals. As the crew change/resupply activities are considered part of normal vessel traffic and are not anticipated to impact marine mammals in a manner that would rise to the level of taking, those activities are not considered further in this document. Additionally, ice-management activities are not anticipated to impact marine mammals in a manner that would rise to the level of taking. This is based on the fact that the propeller rotation *(i.e.,* cavitation) will be similar to that of vessels under normal operations and will not be used at 100 percent power as is the case in other situations rising to the level of taking *(e.g.,* thruster use for dynamic positioning at terminals).

Description of Marine Mammals in the Area of the Specified Activity

The Beaufort Sea supports a diverse assemblage of marine mammals, including: bowhead, gray, beluga, killer (*Orcinus orca*), minke (*Balaenoptera acutorostrata*), and humpback (*Megaptera novaeangliae*) whales; harbor porpoises (*Phocoena phocoena*); ringed, ribbon (*Histriophoca fasciata*), spotted, and bearded seals; polar bears (*Ursus maritimus*); and walruses (*Odobenus rosmarus divergens;* see Table 4–1 in Shell's application). The bowhead and humpback whales are listed as "endangered" under the Endangered Species Act (ESA) and as depleted under the MMPA. Certain stocks or populations of gray, beluga, and killer whales and spotted seals are listed as endangered or are proposed for listing under the ESA; however, none of those stocks or populations occur in the proposed activity area. Additionally, the ribbon seal is considered a "species of concern" under the ESA, and the bearded and ringed seals are "candidate species" under the ESA, meaning they are currently being considered for listing. Both the walrus and the polar bear are managed by the U.S. Fish and Wildlife Service (USFWS) and are not considered further in this proposed IHA notice.

Of these species, six are expected to occur in the area of Shell's proposed operations. These species include: The bowhead, gray, and beluga whales and the ringed, spotted, and bearded seals. The marine mammal species that is likely to be encountered most widely (in space and time) throughout the period of the proposed drilling program is the ringed seal. Bowhead whales are also anticipated to occur in the proposed project area more frequently than the other cetacean species; however, their occurrence is not expected until later in the season. Where available, Shell used density estimates from peer-reviewed literature in the application. In cases where density estimates were not readily available in the peer-reviewed literature, Shell used other methods to derive the estimates. NMFS reviewed the density estimate descriptions and articles from which estimates were derived and requested additional information to better explain the density estimates presented by Shell in its application. This additional information was included in the revised IHA application. The explanation for those derivations and the actual density estimates are described later in this document (see the "Estimated Take by Incidental Harassment" section).

Other cetacean species that have been observed in the Beaufort Sea but are uncommon or rarely identified in the project area include harbor porpoise, narwhal, and killer, minke, humpback, and gray whales. These species could occur in the project area, but each of these species is uncommon or rare in the area and relatively few encounters with these species are expected during the exploration drilling program. The narwhal occurs in Canadian waters and occasionally in the Beaufort Sea, but it is rare there and is not expected to be encountered. There are scattered records of narwhal in Alaskan waters, including reports by subsistence hunters, where the species is considered extralimital (Reeves *et al.,* 2002). Point Barrow, Alaska, is the approximate northeastern extent of the harbor porpoise's regular range (Suydam and George, 1992), though there are extralimital records east to the mouth of the Mackenzie River in the Northwest Territories, Canada, and recent sightings in the Beaufort Sea in the vicinity of Prudhoe Bay during surveys in 2007 and 2008 (Christie *et al.,* 2009). Monnett and Treacy (2005) did not report any harbor porpoise sightings during aerial surveys in the Beaufort Sea from 2002 through 2004. Humpback and minke whales have recently been sighted in the Chukchi Sea but very rarely in the Beaufort Sea. Greene *et al.* (2007) reported and photographed a humpback whale cow/calf pair east of Barrow near Smith Bay in 2007, which is the first known occurrence of humpbacks in the Beaufort Sea. Savarese *et al.* (2009) reported one minke whale sighting in the Beaufort Sea in 2007 and 2008. Ribbon seals do not normally occur in the Beaufort Sea; however, two ribbon seal sightings were reported during vessel-based activities near Prudhoe Bay in 2008 (Savarese *et al.,* 2009). Due to the rarity of these species in the proposed project area and the remote chance they would be affected by Shell's proposed Beaufort Sea drilling activities, these species are not discussed further in this proposed IHA notice.

Shell's application contains information on the status, distribution, seasonal distribution, and abundance of each of the species under NMFS jurisdiction mentioned in this document. When reviewing the application, NMFS determined that the species descriptions provided by Shell correctly characterized the status, distribution, seasonal distribution, and abundance of each species. Please refer to the application for that information *(see* **ADDRESSES**). Additional information can also be found in the NMFS Stock Assessment Reports (SAR). The Alaska 2009 SAR is available at: *http://www.nmfs.noaa.gov/pr/pdfs/sars/ak2009.pdf.*

Potential Effects of the Specified Activity on Marine Mammals

Potential effects of Shell's proposed drilling program in Camden Bay on marine mammals would most likely be acoustic in nature. Petroleum development and associated activities introduce sound into the marine environment. Potential acoustic effects on marine mammals relate to sound produced by drilling activity, vessels, and aircraft. The potential effects of sound from the proposed exploratory drilling program might include one or more of the following: Tolerance; masking of natural sounds; behavioral disturbance; non-auditory physical effects; and, at least in theory, temporary or permanent hearing impairment (Richardson *et al.,* 1995a). However, for reasons discussed later in this document, it is unlikely that there would be any cases of temporary, or especially permanent, hearing impairment resulting from these activities. As outlined in previous NMFS documents, the effects of noise on marine mammals are highly variable, and can be categorized as follows (based on Richardson *et al.,* 1995a):

(1) The noise may be too weak to be heard at the location of the animal (*i.e.,* lower than the prevailing ambient noise level, the hearing threshold of the animal at relevant frequencies, or both);

(2) The noise may be audible but not strong enough to elicit any overt behavioral response;

(3) The noise may elicit reactions of variable conspicuousness and variable relevance to the well being of the marine mammal; these can range from temporary alert responses to active avoidance reactions such as vacating an area at least until the noise event ceases but potentially for longer periods of time;

(4) Upon repeated exposure, a marine mammal may exhibit diminishing responsiveness (habituation), or disturbance effects may persist; the latter is most likely with sounds that are highly variable in characteristics, infrequent, and unpredictable in occurrence, and associated with situations that a marine mammal perceives as a threat;

(5) Any anthropogenic noise that is strong enough to be heard has the potential to reduce (mask) the ability of a marine mammal to hear natural sounds at similar frequencies, including calls from conspecifics, and underwater environmental sounds such as surf noise;

(6) If mammals remain in an area because it is important for feeding, breeding, or some other biologically important purpose even though there is chronic exposure to noise, it is possible that there could be noise-induced physiological stress; this might in turn have negative effects on the well-being or reproduction of the animals involved; and

(7) Very strong sounds have the potential to cause a temporary or permanent reduction in hearing sensitivity. In terrestrial mammals, and presumably marine mammals, received sound levels must far exceed the animal's hearing threshold for there to be any temporary threshold shift (TTS) in its hearing ability. For transient sounds, the sound level necessary to cause TTS is inversely related to the duration of the sound. Received sound levels must be even higher for there to be risk of permanent hearing impairment. In addition, intense acoustic or explosive events may cause trauma to tissues associated with organs vital for hearing, sound production, respiration and other functions. This trauma may include minor to severe hemorrhage.

Brief Background on Marine Mammal Hearing

When considering the influence of various kinds of sound on the marine environment, it is necessary to understand that different kinds of marine life are sensitive to different frequencies of sound. Based on available behavioral data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data, Southall *et al.* (2007) designate "functional hearing groups" for marine mammals and estimate the lower and upper frequencies of functional hearing of the groups. The functional groups and the associated frequencies are indicated below (though, animals are less sensitive to sounds at the outer edge of their functional range and most sensitive to sounds of frequencies within a smaller range somewhere in the middle of their functional hearing range):

- Low frequency cetaceans (13 species of mysticetes): Functional hearing is estimated to occur between approximately 7 Hz and 22 kHz;
- Mid-frequency cetaceans (32 species of dolphins, six species of larger toothed whales, and 19 species of beaked and bottlenose whales): Functional hearing is estimated to occur between approximately 150 Hz and 160 kHz;

• High frequency cetaceans (eight species of true porpoises, six species of river dolphins, *Kogia,* the franciscana, and four species of cephalorhynchids): Functional hearing is estimated to occur between approximately 200 Hz and 180 kHz; and

• Pinnipeds in Water: Functional hearing is estimated to occur between approximately 75 Hz and 75 kHz, with the greatest sensitivity between approximately 700 Hz and 20 kHz.

As mentioned previously in this document, six marine mammal species (three pinniped and three cetacean species) are likely to occur in the proposed drilling area. Of the three cetacean species likely to occur in Shell's project area, two are classified as low frequency cetaceans (*i.e.,* bowhead and gray whales), and one is classified as a mid-frequency cetacean (*i.e.,* beluga whale) (Southall *et al.,* 2007).

Drilling Sounds

Exploratory drilling will be conducted from a vessel specifically designed for such operations in the Arctic. Underwater sound propagation results from the use of generators, drilling machinery, and the rig itself. Received sound levels during vessel-based operations may fluctuate depending on the specific type of activity at a given time and aspect from the vessel. Underwater sound levels may also depend on the specific equipment in operation. Lower sound levels have been reported during well logging than during drilling operations (Greene, 1987b), and underwater sound appeared to be lower at the bow and stern aspects than at the beam (Greene, 1987a).

Most drilling sounds generated from vessel-based operations occur at relatively low frequencies below 600 Hz although tones up to 1,850 Hz were recorded by Greene (1987a) during drilling operations in the Beaufort Sea. At a range of 558 ft (170 m) the 20–1,000 Hz band level was 122–125 dB for the drillship *Explorer I.* Underwater sound levels were slightly higher (134 dB) during drilling activity from the *Northern Explorer II* at a range of 656 ft (200 m), although tones were only recorded below 600 Hz. Underwater sound measurements from the *Kulluk* at 0.62 mi (1 km) were higher (143 dB) than from the other two vessels. Shell used the measurements from the *Northern Explorer II* to model the various sound radii (which are discussed later in this document) for the *Discoverer.* Once on location at the drill sites in Camden Bay, Shell plans to take measurements of the *Discoverer* to quantify the absolute sound levels produced by drilling and to monitor their variations with time, distance, and direction from the drillship. Based on the similarities of the two drillships, NMFS has preliminarily determined that the radii produced by the *Discoverer* would be similar to those recorded for the *Northern Explorer II.*

Vessel Sounds

In addition to the drillship, various types of vessels will be used in support of the operations, including ice-management vessels, anchor handlers, and oil-spill response vessels. Sounds from boats and vessels have been reported extensively (Greene and Moore, 1995; Blackwell and Greene, 2002, 2005, 2006). Numerous measurements of underwater vessel sound have been performed in support of recent industry activity in the Chukchi and Beaufort Seas. Results of these measurements were reported in various 90-day and comprehensive reports since 2007 (*e.g.,* Aerts *et al.,* 2008; Hauser *et al.,* 2008; Brueggeman, 2009; Ireland *et al.,* 2009). For example, Garner and Hannay (2009) estimated sound pressure levels of 100 dB at distances ranging from approximately 1.5 to 2.3 mi (2.4 to 3.7 km) from various types of barges. MacDonald *et al.* (2008) estimated higher underwater SPLs from the seismic vessel *Gilavar* of 120 dB at approximately 13 mi (21 km) from the source, although the sound level was only 150 dB at 85 ft (26 m) from the vessel. Like other industry-generated sound, underwater sound from vessels is generally at relatively low frequencies.

The primary sources of sounds from all vessel classes are propeller cavitation, propeller singing, and propulsion or other machinery. Propeller cavitation is usually the dominant noise source for vessels (Ross, 1976). Propeller cavitation and singing are produced outside the hull, whereas propulsion or other machinery noise originates inside the hull. There are additional sounds produced by vessel activity, such as pumps, generators, flow noise from water passing over the hull, and bubbles breaking in the wake. Icebreakers contribute greater sound levels during ice-breaking activities than ships of similar size during normal operation in open water (Richardson *et al.,* 1995a). This higher sound production results from the greater amount of power and propeller cavitation required when operating in thick ice.

Sound levels during ice-management activities would not be as intense as during icebreaking, and the resulting effects to marine species would be less significant in comparison. During ice-management, the vessel's propeller is rotating at approximately 15–20 percent of the vessel's propeller rotation capacity. Instead of actually breaking ice, during ice-management, the vessel redirects and repositions the ice by pushing it away from the direction of the drillship at slow speeds so that the ice floe does not slip past the vessel bow. Basically, ice-management occurs at slower speed, lower power, and slower propeller rotation speed (*i.e.,* lower cavitation), allowing for fewer repositions of the vessel, thereby reducing cavitation effects in the water than would occur during icebreaking. Once on location at the drill sites in Camden Bay, Shell plans to measure the sound levels produced by vessels operating in support of drilling operations. These vessels will include crew change vessels, tugs, ice-management vessels, and spill response vessels.

Aircraft Sound

Helicopters may be used for personnel and equipment transport to and from the drillship. Under calm conditions, rotor and engine sounds are coupled into the water within a 26° cone beneath the aircraft. Some of the sound will transmit beyond the immediate area, and some sound will enter the water outside the 26° area when the sea surface is rough. However, scattering and absorption will limit lateral propagation in the shallow water.

Dominant tones in noise spectra from helicopters are generally below 500 Hz (Greene and Moore, 1995). Harmonics of the main rotor and tail rotor usually dominate the sound from helicopters; however, many additional tones associated with the engines and other rotating parts are sometimes present.

Because of doppler shift effects, the frequencies of tones received at a stationary site diminish when an aircraft passes overhead. The apparent frequency is increased while the aircraft approaches and is reduced while it moves away.

Aircraft flyovers are not heard underwater for very long, especially when compared to how long they are heard in air as the aircraft approaches an observer. Helicopters flying to and from the drillship will generally maintain straight-line routes at altitudes of at least 1,000 ft (305 m), thereby limiting the received levels at and below the surface.

Tolerance

Numerous studies have shown that underwater sounds from industry activities are often readily detectable by marine mammals in the water at

distances of many kilometers. Numerous studies have also shown that marine mammals at distances more than a few kilometers away often show no apparent response to industry activities of various types (Miller *et al.*, 2005; Bain and Williams, 2006). This is often true even in cases when the sounds must be readily audible to the animals based on measured received levels and the hearing sensitivity of that mammal group. Although various baleen whales, toothed whales, and (less frequently) pinnipeds have been shown to react behaviorally to underwater sound such as airgun pulses or vessels under some conditions, at other times mammals of all three types have shown no overt reactions (*e.g.*, Malme *et al.*, 1986; Richardson *et al.*, 1995; Madsen and Mohl, 2000; Croll *et al.*, 2001; Jacobs and Terhune, 2002; Madsen *et al.*, 2002; Miller *et al.*, 2005). In general, pinnipeds and small odontocetes seem to be more tolerant of exposure to some types of underwater sound than are baleen whales. Richardson *et al.* (1995a) found that vessel noise does not seem to strongly affect pinnipeds that are already in the water. Richardson *et al.* (1995a) went on to explain that seals on haul-outs sometimes respond strongly to the presence of vessels and at other times appear to show considerable tolerance of vessels, and (Brueggeman et al., 1992; cited in Richardson *et al.*, 1995a) observed ringed seals hauled out on ice pans displaying short-term escape reactions when a ship approached within 0.25–0.5 mi (0.4–0.8 km).

Masking

The term "masking" refers to the obscuring of sounds of interest by interfering sounds, generally at similar frequencies. Masking effects of underwater sounds on marine mammal calls and other natural sounds are expected to be limited. For example, beluga whales primarily use high-frequency sounds to communicate and locate prey; therefore, masking by low-frequency sounds associated with drilling activities is not expected to occur (Gales, 1982, as cited in Shell, 2009). If the distance between communicating whales does not exceed their distance from the drilling activity, the likelihood of potential impacts from masking would be low (Gales, 1982, as cited in Shell, 2009). At distances greater than 660–1,300 ft (200–400 m), recorded sounds from drilling activities did not affect behavior of beluga whales, even though the sound energy level and frequency were such that it could be heard several kilometers away (Richardson *et al.*, 1995b). This exposure resulted in whales being deflected from the sound energy and changing behavior. These minor changes are not expected to affect the beluga whale population (Richardson *et al.*, 1991; Richard *et al.*, 1998). Brewer *et al.* (1993) observed belugas within 2.3 mi (3.7 km) of the drilling unit *Kulluk* during drilling; however, the authors do not describe any behaviors that may have been exhibited by those animals. Please refer to the Arctic Multiple-Sale Draft Environmental Impact Statement (USDOI MMS, 2008), available on the Internet at: *http://www.mms.gov/alaska/ref/EIS%20EA/ArcticMultiSale_209/_DEIS.htm*, for more detailed information.

There is evidence of other marine mammal species continuing to call in the presence of industrial activity. For example, bowhead whale calls are frequently detected in the presence of seismic pulses, although the number of calls detected may sometimes be reduced (Richardson *et al.*, 1986; Greene *et al.*, 1999; Blackwell *et al.*, 2009). Additionally, annual acoustical monitoring near BP's Northstar production facility during the fall bowhead migration westward through the Beaufort Sea has recorded thousands of calls each year (for examples, see Richardson *et al.*, 2007; Aerts and Richardson, 2008). Construction, maintenance, and operational activities have been occurring from this facility for nearly 10 years. To compensate and reduce masking, some mysticetes may alter the frequencies of their communication sounds (Richardson *et al.*, 1995a; Parks *et al.*, 2007). Masking processes in baleen whales are not amenable to laboratory study, and no direct measurements on hearing sensitivity are available for these species. It is not currently possible to determine with precision the potential consequences of temporary or local background noise levels. However, Parks *et al.* (2007) found that right whales altered their vocalizations, possibly in response to background noise levels. For species that can hear over a relatively broad frequency range, as is presumed to be the case for mysticetes, a narrow band source may only cause partial masking. Richardson *et al.* (1995a) note that a bowhead whale 12.4 mi (20 km) from a human sound source, such as that produced during oil and gas industry activities, might hear strong calls from other whales within approximately 12.4 mi (20 km), and a whale 3.1 mi (5 km) from the source might hear strong calls from whales within approximately 3.1 mi (5 km). Additionally, masking is more likely to occur closer to a sound source, and distant anthropogenic sound is less likely to mask short-distance acoustic communication (Richardson *et al.*, 1995a).

Although some masking by marine mammal species in the area may occur, the extent of the masking interference will depend on the spatial relationship of the animal and Shell's activity. If, as described later in this document, certain species avoid the proposed drilling locations, impacts from masking will be low.

Behavioral Disturbance Reactions

Behavioral responses to sound are highly variable and context-specific. Many different variables can influence an animal's perception of and response to (in both nature and magnitude) an acoustic event. An animal's prior experience with a sound or sound source affects whether it is less likely (habituation) or more likely (sensitization) to respond to certain sounds in the future (animals can also be innately pre-disposed to respond to certain sounds in certain ways; Southall *et al.*, 2007). Related to the sound itself, the perceived nearness of the sound, bearing of the sound (approaching vs. retreating), similarity of a sound to biologically relevant sounds in the animal's environment *(i.e.*, calls of predators, prey, or conspecifics), and familiarity of the sound may affect the way an animal responds to the sound (Southall *et al.,* 2007). Individuals (of different age, gender, reproductive status, *etc.*) among most populations will have variable hearing capabilities, and differing behavioral sensitivities to sounds that will be affected by prior conditioning, experience, and current activities of those individuals. Often, specific acoustic features of the sound and contextual variables (*i.e.*, proximity, duration, or recurrence of the sound or the current behavior that the marine mammal is engaged in or its prior experience), as well as entirely separate factors such as the physical presence of a nearby vessel, may be more relevant to the animal's response than the received level alone.

Exposure of marine mammals to sound sources can result in (but is not limited to) no response or any of the following observable responses: Increased alertness; orientation or attraction to a sound source; vocal modifications; cessation of feeding; cessation of social interaction; alteration of movement or diving behavior; avoidance; habitat abandonment (temporary or permanent); and, in severe cases, panic, flight, stampede, or stranding, potentially resulting in death

(Southall *et al.*, 2007). On a related note, many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hr cycle). Behavioral reactions to noise exposure (such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.*, 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.*, 2007).

Detailed studies regarding responses to anthropogenic sound have been conducted on humpback, gray, and bowhead whales and ringed seals. Less detailed data are available for some other species of baleen whales, sperm whales, small toothed whales, and sea otters. The following sub-sections provide examples of behavioral responses that provide an idea of the variability in behavioral responses that would be expected given the differential sensitivities of marine mammal species to sound and the wide range of potential acoustic sources to which a marine mammal may be exposed.

Baleen Whales—Baleen whale responses to pulsed sound (*e.g.*, seismic airguns) have been studied more thoroughly than responses to continuous sound (*e.g.,* drillships). Baleen whales generally tend to avoid operating airguns, but avoidance radii are quite variable. Whales are often reported to show no overt reactions to pulses from large arrays of airguns at distances beyond a few kilometers, even though the airgun pulses remain well above ambient noise levels out to much greater distances (Miller *et al.*, 2005). However, baleen whales exposed to strong noise pulses often react by deviating from their normal migration route (Richardson *et al.*, 1999). Migrating gray and bowhead whales were observed avoiding the sound source by displacing their migration route to varying degrees but within the natural boundaries of the migration corridors (Schick and Urban, 2000; Richardson *et al.*, 1999; Malme *et al.*, 1983).

Richardson *et al.* (1995b) reported changes in surfacing and respiration behavior and the occurrence of turns during surfacing in bowhead whales exposed to playback of underwater sound from drilling activities. These behavioral effects were localized and occurred at distances up to 1.2–2.5 mi (2–4 km). Some bowheads appeared to divert from their migratory path after exposure to projected icebreaker sounds. Other bowheads, however, tolerated projected icebreaker sound at levels 20 dB and more above ambient sound levels. The source level of the projected sound, however, was much less than that of an actual icebreaker, and reaction distances to actual icebreaking may be much greater than those reported here for projected sounds.

Brewer *et al.* (1993) and Hall *et al.* (1994) reported numerous sightings of marine mammals including bowhead whales in the vicinity of offshore drilling operations in the Beaufort Sea. One bowhead whale sighting was reported within approximately 1,312 ft (400 m) of a drilling vessel although other sightings were at much greater distances. Few bowheads were recorded near industrial activities by aerial observers, but observations by surface observers suggested that bowheads may have been closer to industrial activities than was suggested by results of aerial observations.

Richardson *et al.* (2008) reported a slight change in the distribution of bowhead whale calls in response to operational sounds on BP's Northstar Island. The southern edge of the call distribution ranged from 0.47 to 1.46 mi (0.76 to 2.35 km) farther offshore, apparently in response to industrial sound levels. This result, however, was only achieved after intensive statistical analyses, and it is not clear that this represented a biologically significant effect.

Patenaude *et al.* (2002) reported fewer behavioral responses to aircraft overflights by bowhead compared to beluga whales. Behaviors classified as reactions consisted of short surfacings, immediate dives or turns, changes in behavior state, vigorous swimming, and breaching. Most bowhead reaction resulted from exposure to helicopter activity and little response to fixed-wing aircraft was observed. Most reactions occurred when the helicopter was at altitudes ≤ 492 ft (150 m) and lateral distances ≤ 820 ft (250 m; Nowacek *et al.*, 2007). Restriction on aircraft altitude will be part of the proposed mitigation measures (described in the "Proposed Mitigation" section later in this document) during the proposed drilling activities, and overflights are likely to have little or no disturbance effects on baleen whales. Any disturbance that may occur would likely be temporary and localized.

Southall *et al.* (2007, Appendix C) reviewed a number of papers describing the responses of marine mammals to non-pulsed sound, such as that produced during exploratory drilling operations. In general, little or no response was observed in animals exposed at received levels from 90–120 dB re 1 μPa (rms). Probability of avoidance and other behavioral effects increased when received levels were from 120–160 dB re 1 μPa (rms). Some of the relevant reviews contained in Southall *et al.* (2007) are summarized next.

Baker *et al.* (1982) reported some avoidance by humpback whales to vessel noise when received levels were 110–120 dB (rms) and clear avoidance at 120–140 dB (sound measurements were not provided by Baker but were based on measurements of identical vessels by Miles and Malme, 1983).

Malme *et al.* (1983, 1984) used playbacks of sounds from helicopter overflight and drilling rigs and platforms to study behavioral effects on migrating gray whales. Received levels exceeding 120 dB induced avoidance reactions. Malme *et al.* (1984) calculated 10 percent, 50 percent, and 90 percent probabilities of gray whale avoidance reactions at received levels of 110, 120, and 130 dB, respectively. Malme *et al.* (1986) observed the behavior of feeding gray whales during four experimental playbacks of drilling sounds (50 to 315 Hz; 21-min overall duration and 10 percent duty cycle; source levels of 156–162 dB). In two cases for received levels of 100–110 dB, no behavioral reaction was observed. However, avoidance behavior was observed in two cases where received levels were 110–120 dB.

Richardson *et al.* (1990) performed 12 playback experiments in which bowhead whales in the Alaskan Arctic were exposed to drilling sounds. Whales generally did not respond to exposures in the 100 to 130 dB range, although there was some indication of minor behavioral changes in several instances.

McCauley *et al.* (1996) reported several cases of humpback whales responding to vessels in Hervey Bay, Australia. Results indicated clear avoidance at received levels between 118 to 124 dB in three cases for which response and received levels were observed/measured.

Palka and Hammond (2001) analyzed line transect census data in which the orientation and distance off transect line were reported for large numbers of minke whales. The authors developed a method to account for effects of animal movement in response to sighting platforms. Minor changes in locomotion speed, direction, and/or diving profile were reported at ranges from 1,847 to 2,352 ft (563 to 717 m) at received levels of 110 to 120 dB.

Biassoni *et al.* (2000) and Miller *et al.* (2000) reported behavioral observations

for humpback whales exposed to a low-frequency sonar stimulus (160- to 330-Hz frequency band; 42-s tonal signal repeated every 6 min; source levels 170 to 200 dB) during playback experiments. Exposure to measured received levels ranging from 120 to 150 dB resulted in variability in humpback singing behavior. Croll *et al.* (2001) investigated responses of foraging fin and blue whales to the same low frequency active sonar stimulus off southern California. Playbacks and control intervals with no transmission were used to investigate behavior and distribution on time scales of several weeks and spatial scales of tens of kilometers. The general conclusion was that whales remained feeding within a region for which 12 to 30 percent of exposures exceeded 140 dB.

Frankel and Clark (1998) conducted playback experiments with wintering humpback whales using a single speaker producing a low-frequency "M-sequence" (sine wave with multiple-phase reversals) signal in the 60 to 90 Hz band with output of 172 dB at 1 m. For 11 playbacks, exposures were between 120 and 130 dB re 1 μPa (rms) and included sufficient information regarding individual responses. During eight of the trials, there were no measurable differences in tracks or bearings relative to control conditions, whereas on three occasions, whales either moved slightly away from (n = 1) or towards (n = 2) the playback speaker during exposure. The presence of the source vessel itself had a greater effect than did the M-sequence playback.

Finally, Nowacek *et al.* (2004) used controlled exposures to demonstrate behavioral reactions of northern right whales to various non-pulse sounds. Playback stimuli included ship noise, social sounds of conspecifics, and a complex, 18-min "alert" sound consisting of repetitions of three different artificial signals. Ten whales were tagged with calibrated instruments that measured received sound characteristics and concurrent animal movements in three dimensions. Five out of six exposed whales reacted strongly to alert signals at measured received levels between 130 and 150 dB (*i.e.*, ceased foraging and swam rapidly to the surface). Two of these individuals were not exposed to ship noise, and the other four were exposed to both stimuli. These whales reacted mildly to conspecific signals. Seven whales, including the four exposed to the alert stimulus, had no measurable response to either ship sounds or actual vessel noise.

Toothed Whales—Most toothed whales have the greatest hearing sensitivity at frequencies much higher than that of baleen whales and may be less responsive to low-frequency sound commonly associated with oil and gas industry exploratory drilling activities. Richardson *et al.* (1995b) reported that beluga whales did not show any apparent reaction to playback of underwater drilling sounds at distances greater than 656–1,312 ft (200–400 m). Reactions included slowing down, milling, or reversal of course after which the whales continued past the projector, sometimes within 164–328 ft (50–100 m). The authors concluded (based on a small sample size) that the playback of drilling sounds had no biologically significant effects on migration routes of beluga whales migrating through pack ice and along the seaward side of the nearshore lead east of Pt. Barrow in spring.

At least six of 17 groups of beluga whales appeared to alter their migration path in response to underwater playbacks of icebreaker sound (Richardson *et al.*, 1995b). Received levels from the icebreaker playback were estimated at 78–84 dB in the 1/3-octave band centered at 5,000 Hz, or 8–14 dB above ambient. If beluga whales reacted to an actual icebreaker at received levels of 80 dB, reactions would be expected to occur at distances on the order of 6.2 mi (10 km). Finley *et al.* (1990) also reported beluga avoidance of icebreaker activities in the Canadian High Arctic at distances of 22–31 mi (35–50 km). In addition to avoidance, changes in dive behavior and pod integrity were also noted. However, while the *Vladimir Ignatjuk* (an icebreaker) is anticipated to be one of the vessels attending the *Discoverer,* it will only be conducting ice-management activities (which were described in the "Description of the Specified Activity" section earlier in this document) and not physical breaking of ice. Thus, NMFS does not anticipate that marine mammals would exhibit the types of behavioral reactions as those noted in the aforementioned studies.

Patenaude *et al.* (2002) reported that beluga whales appeared to be more responsive to aircraft overflights than bowhead whales. Changes were observed in diving and respiration behavior, and some whales veered away when a helicopter passed at ≤820 ft (250 m) lateral distance at altitudes up to 492 ft (150 m). However, some belugas showed no reaction to the helicopter. Belugas appeared to show less response to fixed-wing aircraft than to helicopter overflights.

In reviewing responses of cetaceans with best hearing in mid-frequency ranges, which includes toothed whales, Southall *et al.* (2007) reported that combined field and laboratory data for mid-frequency cetaceans exposed to non-pulse sounds did not lead to a clear conclusion about received levels coincident with various behavioral responses. In some settings, individuals in the field showed profound (significant) behavioral responses to exposures from 90 to 120 dB, while others failed to exhibit such responses for exposure to received levels from 120 to 150 dB. Contextual variables other than exposure received level, and probable species differences, are the likely reasons for this variability. Context, including the fact that captive subjects were often directly reinforced with food for tolerating noise exposure, may also explain why there was great disparity in results from field and laboratory conditions—exposures in captive settings generally exceeded 170 dB before inducing behavioral responses. A summary of some of the relevant material reviewed by Southall *et al.* (2007) is next.

LGL and Greeneridge (1986) and Finley *et al.* (1990) documented belugas and narwhals congregated near ice edges reacting to the approach and passage of ice-breaking ships. Beluga whales responded to oncoming vessels by (1) fleeing at speeds of up to 12.4 mi/hr (20 km/hr) from distances of 12.4–50 mi (20–80 km), (2) abandoning normal pod structure, and (3) modifying vocal behavior and/or emitting alarm calls. Narwhals, in contrast, generally demonstrated a "freeze" response, lying motionless or swimming slowly away (as far as 23 mi [37 km] down the ice edge), huddling in groups, and ceasing sound production. There was some evidence of habituation and reduced avoidance 2 to 3 days after onset.

The 1982 season observations by LGL and Greeneridge (1986) involved a single passage of an icebreaker with both ice-based and aerial measurements on June 28, 1982. Four groups of narwhals (n = 9 to 10, 7, 7, and 6) responded when the ship was 4 mi (6.4 km) away (received levels of approximately 100 dB in the 150- to 1,150-Hz band). At a later point, observers sighted belugas moving away from the source at more than 12.4 mi (20 km; received levels of approximately 90 dB in the 150- to 1,150-Hz band). The total number of animals observed fleeing was about 300, suggesting approximately 100 independent groups (of three individuals each). No whales were sighted the following day, but some were sighted on June 30, with ship noise audible at spectrum levels of approximately 55 dB/Hz (up to 4 kHz).

Observations during 1983 (LGL and Greeneridge, 1986) involved two ice-breaking ships with aerial survey and ice-based observations during seven sampling periods. Narwhals and belugas generally reacted at received levels ranging from 101 to 121 dB in the 20- to 1,000-Hz band and at a distance of up to 40.4 mi (65 km). Large numbers (100s) of beluga whales moved out of the area at higher received levels. As noise levels from icebreaking operations diminished, a total of 45 narwhals returned to the area and engaged in diving and foraging behavior. During the final sampling period, following an 8-h quiet interval, no reactions were seen from 28 narwhals and 17 belugas (at received levels ranging up to 115 dB).

The final season (1984) reported in LGL and Greeneridge (1986) involved aerial surveys before, during, and after the passage of two ice-breaking ships. During operations, no belugas and few narwhals were observed in an area approximately 16.8 mi (27 km) ahead of the vessels, and all whales sighted over 12.4–50 mi (20–80 km) from the ships were swimming strongly away. Additional observations confirmed the spatial extent of avoidance reactions to this sound source in this context.

Buckstaff (2004) reported elevated dolphin whistle rates with received levels from oncoming vessels in the 110 to 120 dB range in Sarasota Bay, Florida. These hearing thresholds were apparently lower than those reported by a researcher listening with towed hydrophones. Morisaka *et al.* (2005) compared whistles from three populations of Indo-Pacific bottlenose dolphins. One population was exposed to vessel noise with spectrum levels of approximately 85 dB/Hz in the 1- to 22-kHz band (broadband received levels approximately 128 dB) as opposed to approximately 65 dB/Hz in the same band (broadband received levels approximately 108 dB) for the other two sites. Dolphin whistles in the noisier environment had lower fundamental frequencies and less frequency modulation, suggesting a shift in sound parameters as a result of increased ambient noise.

Morton and Symonds (2002) used census data on killer whales in British Columbia to evaluate avoidance of non-pulse acoustic harassment devices (AHDs). Avoidance ranges were about 2.5 mi (4 km). Also, there was a dramatic reduction in the number of days "resident" killer whales were sighted during AHD-active periods compared to pre- and post-exposure periods and a nearby control site.

Awbrey and Stewart (1983) played back semi-submersible drillship sounds (source level: 163 dB) to belugas in Alaska. They reported avoidance reactions at 984 and 4,921 ft (300 and 1,500 m) and approach by groups at a distance of 2.2 mi (3.5 km; received levels approximately 110 to 145 dB over these ranges assuming a 15 log R transmission loss). Similarly, Richardson *et al.* (1990) played back drilling platform sounds (source level: 163 dB) to belugas in Alaska. They conducted aerial observations of eight individuals among approximately 100 spread over an area several hundred meters to several kilometers from the sound source and found no obvious reactions. Moderate changes in movement were noted for three groups swimming within 656 ft (200 m) of the sound projector.

Two studies deal with issues related to changes in marine mammal vocal behavior as a function of variable background noise levels. Foote *et al.* (2004) found increases in the duration of killer whale calls over the period 1977 to 2003, during which time vessel traffic in Puget Sound, and particularly whale-watching boats around the animals, increased dramatically. Scheifele *et al.* (2005) demonstrated that belugas in the St. Lawrence River increased the levels of their vocalizations as a function of the background noise level (the "Lombard Effect").

Several researchers conducting laboratory experiments on hearing and the effects of non-pulse sounds on hearing in mid-frequency cetaceans have reported concurrent behavioral responses. Nachtigall *et al.* (2003) reported that noise exposures up to 179 dB and 55-min duration affected the trained behaviors of a bottlenose dolphin participating in a TTS experiment. Finneran and Schlundt (2004) provided a detailed, comprehensive analysis of the behavioral responses of belugas and bottlenose dolphins to 1-s tones (received levels 160 to 202 dB) in the context of TTS experiments. Romano *et al.* (2004) investigated the physiological responses of a bottlenose dolphin and a beluga exposed to these tonal exposures and demonstrated a decrease in blood cortisol levels during a series of exposures between 130 and 201 dB. Collectively, the laboratory observations suggested the onset of a behavioral response at higher received levels than did field studies. The differences were likely related to the very different conditions and contextual variables between untrained, free-ranging individuals vs. laboratory subjects that were rewarded with food for tolerating noise exposure.

Pinnipeds—Pinnipeds generally seem to be less responsive to exposure to industrial sound than most cetaceans. Pinniped responses to underwater sound from some types of industrial activities such as seismic exploration appear to be temporary and localized (Harris *et al.*, 2001; Reiser *et al.*, 2009).

Blackwell *et al.* (2004) reported little or no reaction of ringed seals in response to pile-driving activities during construction of a man-made island in the Beaufort Sea. Ringed seals were observed swimming as close as 151 ft (46 m) from the island and may have been habituated to the sounds which were likely audible at distances <9,842 ft (3,000 m) underwater and 0.3 mi (0.5 km) in air. Moulton *et al.* (2003) reported that ringed seal densities on ice in the vicinity of a man-made island in the Beaufort Sea did not change significantly before and after construction and drilling activities.

Southall *et al.* (2007) reviewed literature describing responses of pinnipeds to non-pulsed sound and reported that the limited data suggest exposures between approximately 90 and 140 dB generally do not appear to induce strong behavioral responses in pinnipeds exposed to non-pulse sounds in water; no data exist regarding exposures at higher levels. It is important to note that among these studies, there are some apparent differences in responses between field and laboratory conditions. In contrast to the mid-frequency odontocetes, captive pinnipeds responded more strongly at lower levels than did animals in the field. Again, contextual issues are the likely cause of this difference.

Jacobs and Terhune (2002) observed harbor seal reactions to AHDs (source level in this study was 172 dB) deployed around aquaculture sites. Seals were generally unresponsive to sounds from the AHDs. During two specific events, individuals came within 141 and 144 ft (43 and 44 m) of active AHDs and failed to demonstrate any measurable behavioral response; estimated received levels based on the measures given were approximately 120 to 130 dB.

Costa *et al.* (2003) measured received noise levels from an Acoustic Thermometry of Ocean Climate (ATOC) program sound source off northern California using acoustic data loggers placed on translocated elephant seals. Subjects were captured on land, transported to sea, instrumented with archival acoustic tags, and released such that their transit would lead them near an active ATOC source (at 939-m depth; 75-Hz signal with 37.5-Hz bandwidth; 195 dB maximum source level, ramped

up from 165 dB over 20 min) on their return to a haul-out site. Received exposure levels of the ATOC source for experimental subjects averaged 128 dB (range 118 to 137) in the 60- to 90-Hz band. None of the instrumented animals terminated dives or radically altered behavior upon exposure, but some statistically significant changes in diving parameters were documented in nine individuals. Translocated northern elephant seals exposed to this particular non-pulse source began to demonstrate subtle behavioral changes at exposure to received levels of approximately 120 to 140 dB.

Kastelein *et al.* (2006) exposed nine captive harbor seals in an approximately 82 × 98 ft (25 × 30 m) enclosure to non-pulse sounds used in underwater data communication systems (similar to acoustic modems). Test signals were frequency modulated tones, sweeps, and bands of noise with fundamental frequencies between 8 and 16 kHz; 128 to 130 [± 3] dB source levels; 1- to 2-s duration [60–80 percent duty cycle]; or 100 percent duty cycle. They recorded seal positions and the mean number of individual surfacing behaviors during control periods (no exposure), before exposure, and in 15-min experimental sessions (n = 7 exposures for each sound type). Seals generally swam away from each source at received levels of approximately 107 dB, avoiding it by approximately 16 ft (5 m), although they did not haul out of the water or change surfacing behavior. Seal reactions did not appear to wane over repeated exposure (*i.e.,* there was no obvious habituation), and the colony of seals generally returned to baseline conditions following exposure. The seals were not reinforced with food for remaining in the sound field.

Hearing Impairment and Other Physiological Effects

Temporary or permanent hearing impairment is a possibility when marine mammals are exposed to very strong sounds. Non-auditory physiological effects might also occur in marine mammals exposed to strong underwater sound. Possible types of non-auditory physiological effects or injuries that theoretically might occur in mammals close to a strong sound source include stress, neurological effects, bubble formation, and other types of organ or tissue damage. It is possible that some marine mammal species (*i.e.,* beaked whales) may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds. However, as discussed later in this document, there is no definitive evidence that any of these effects occur even for marine mammals in close proximity to industrial sound sources, and beaked whales do not occur in the proposed activity area. The following subsections discuss in somewhat more detail the possibilities of TTS, permanent threshold shift (PTS), and non-auditory physiological effects.

TTS—TTS is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises and a sound must be stronger in order to be heard. At least in terrestrial mammals, TTS can last from minutes or hours to (in cases of strong TTS) days. For sound exposures at or somewhat above the TTS threshold, hearing sensitivity in both terrestrial and marine mammals recovers rapidly after exposure to the noise ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals, and none of the published data concern TTS elicited by exposure to multiple pulses of sound.

For toothed whales exposed to single, short pulses, the TTS threshold appears to be, to a first approximation, a function of the energy content of the pulse (Finneran *et al.,* 2002, 2005). Given the available data, the received level of a single seismic pulse (with no frequency weighting) might need to be approximately 186 dB re 1 $\mu Pa^2 \cdot s$ (*i.e.,* 186 dB sound exposure level [SEL]) in order to produce brief, mild TTS. Exposure to several strong seismic pulses that each have received levels near 175–180 dB SEL might result in slight TTS in a small odontocete, assuming the TTS threshold is (to a first approximation) a function of the total received pulse energy. Given that the SPL is approximately 10–15 dB higher than the SEL value for the same pulse, an odontocete would need to be exposed to a sound level of 190 dB re 1 µPa (rms) in order to incur TTS.

For baleen whales, there are no data, direct or indirect, on levels or properties of sound that are required to induce TTS. The frequencies to which baleen whales are most sensitive are lower than those to which odontocetes are most sensitive, and natural background noise levels at those low frequencies tend to be higher. Marine mammals can hear sounds at varying frequency levels. However, sounds that are produced in the frequency range at which an animal hears the best do not need to be as loud as sounds in less functional frequencies to be detected by the animal. As a result, auditory thresholds of baleen whales within their frequency band of best hearing are believed to be higher (less sensitive) than are those of odontocetes at their best frequencies (Clark and Ellison, 2004), meaning that baleen whales require sounds to be louder (i.e., higher dB levels) than odontocetes in the frequency ranges at which each group hears the best. From this, it is suspected that received levels causing TTS onset may also be higher in baleen whales. Since current NMFS practice assumes the same thresholds for the onset of hearing impairment in both odontocetes and mysticetes, the threshold is likely conservative for mysticetes.

In free-ranging pinnipeds, TTS thresholds associated with exposure to brief pulses (single or multiple) of underwater sound have not been measured. However, systematic TTS studies on captive pinnipeds have been conducted (Bowles *et al.,* 1999; Kastak *et al.,* 1999, 2005, 2007; Schusterman *et al.,* 2000; Finneran *et al.,* 2003; Southall *et al.,* 2007). Kastak *et al.* (1999) reported TTS of approximately 4–5 dB in three species of pinnipeds (harbor seal, Californian sea lion, and northern elephant seal) after underwater exposure for approximately 20 minutes to noise with frequencies ranging from 100 Hz to 2,000 Hz at received levels 60–75 dB above hearing threshold. This approach allowed similar effective exposure conditions to each of the subjects, but resulted in variable absolute exposure values depending on subject and test frequency. Recovery to near baseline levels was reported within 24 hours of noise exposure (Kastak *et al.,* 1999). Kastak *et al.* (2005) followed up on their previous work using higher sensitive levels and longer exposure times (up to 50-min) and corroborated their previous findings. The sound exposures necessary to cause slight threshold shifts were also determined for two California sea lions and a juvenile elephant seal exposed to underwater sound for similar duration. The sound level necessary to cause TTS in pinnipeds depends on exposure duration, as in other mammals; with longer exposure, the level necessary to elicit TTS is reduced (Schusterman *et al.,* 2000; Kastak *et al.,* 2005, 2007). For very short exposures (e.g., to a single sound pulse), the level necessary to cause TTS is very high (Finneran *et al.,* 2003). For pinnipeds exposed to in-air sounds, auditory fatigue has been measured in response to single pulses and to non-pulse noise (Southall *et al.,* 2007), although high exposure levels were required to induce TTS-onset (SEL: 129 dB re: 20 $\mu Pa^2 \cdot s$; Bowles *et al.,* unpub. data).

NMFS (1995, 2000) concluded that cetaceans and pinnipeds should not be exposed to pulsed underwater noise at

received levels exceeding, respectively, 180 and 190 dB re 1 µPa (rms). The established 180- and 190-dB re 1 µPa (rms) criteria are not considered to be the levels above which TTS might occur. Rather, they are the received levels above which, in the view of a panel of bioacoustics specialists convened by NMFS before TTS measurements for marine mammals started to become available, one could not be certain that there would be no injurious effects, auditory or otherwise, to marine mammals. Based on the summary provided here and the fact that modeling indicates the back-propagated source level for the drillship to be 175 dB re 1 µPa at 1 m, TTS is not expected to occur in any marine mammal species that may occur in the proposed drilling area since the source level will not reach levels thought to induce even mild TTS.

PTS—When PTS occurs, there is physical damage to the sound receptors in the ear. In some cases, there can be total or partial deafness, whereas in other cases, the animal has an impaired ability to hear sounds in specific frequency ranges.

There is no specific evidence that exposure to underwater industrial sound associated with oil exploration can cause PTS in any marine mammal (*see* Southall *et al.,* 2007). However, given the possibility that mammals might incur TTS, there has been further speculation about the possibility that some individuals occurring very close to such activities might incur PTS. Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage in terrestrial mammals. Relationships between TTS and PTS thresholds have not been studied in marine mammals but are assumed to be similar to those in humans and other terrestrial mammals. PTS might occur at a received sound level at least several decibels above that inducing mild TTS.

It is highly unlikely that marine mammals could receive sounds strong enough (and over a sufficient duration) to cause PTS during the proposed exploratory drilling program. As mentioned previously in this document, the source levels of the drillship are not considered strong enough to cause even slight TTS. Given the higher level of sound necessary to cause PTS, it is even less likely that PTS could occur. In fact, based on the modeled source levels for the drillship, the levels immediately adjacent to the drillship may not be sufficient to induce PTS, even if the animals remain in the immediate vicinity of the activity. The modeled source level from a similar drillship (*i.e.,* the *Northern Explorer II*) suggests that marine mammals located immediately adjacent to a drillship such as the *Discoverer* would likely not be exposed to received sound levels of a magnitude strong enough to induce PTS, even if the animals remain in the immediate vicinity of the proposed activity location for a prolonged period of time.

Non-auditory Physiological Effects—Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to strong underwater sound include stress, neurological effects, bubble formation, and other types of organ or tissue damage. If any such effects do occur, they probably would be limited to unusual situations when animals might be exposed at close range for unusually long periods. It is doubtful that any single marine mammal would be exposed to strong sounds for sufficiently long that significant physiological stress would develop.

Until recently, it was assumed that diving marine mammals are not subject to the bends or air embolism. This possibility was first explored at a workshop (Gentry [ed.], 2002) held to discuss whether the stranding of beaked whales in the Bahamas in 2000 (Balcomb and Claridge, 2001; NOAA and USN, 2001) might have been related to bubble formation in tissues caused by exposure to noise from naval sonar. However, the opinions were inconclusive. Jepson *et al.* (2003) first suggested a possible link between mid-frequency sonar activity and acute and chronic tissue damage that results from the formation in vivo of gas bubbles, based on the beaked whale stranding in the Canary Islands in 2002 during naval exercises. Fernandez *et al.* (2005a) showed those beaked whales did indeed have gas bubble-associated lesions as well as fat embolisms. Fernandez *et al.* (2005b) also found evidence of fat embolism in three beaked whales that stranded 62 mi (100 km) north of the Canaries in 2004 during naval exercises. Examinations of several other stranded species have also revealed evidence of gas and fat embolisms (Arbelo *et al.,* 2005; Jepson *et al.,* 2005a; Mendez *et al.,* 2005). Most of the afflicted species were deep divers. There is speculation that gas and fat embolisms may occur if cetaceans ascend unusually quickly when exposed to aversive sounds or if sound in the environment causes the destabilization of existing bubble nuclei (Potter, 2004; Arbelo *et al.,* 2005; Fernandez *et al.,* 2005a; Jepson *et al.,* 2005b). Even if gas and fat embolisms can occur during exposure to mid-frequency sonar, there is no evidence that that type of effect occurs in response to the types of sound produced during the proposed exploratory activities. Also, most evidence for such effects has been in beaked whales, which do not occur in the proposed survey area.

The low levels of continuous sound that will be produced by the drillship are not expected to cause such effects. Additionally, marine mammals that show behavioral avoidance of the proposed activities, including most baleen whales, some odontocetes (including belugas), and some pinnipeds, are especially unlikely to incur auditory impairment or other physical effects.

Stranding and Mortality

Marine mammals close to underwater detonations of high explosives can be killed or severely injured, and the auditory organs are especially susceptible to injury (Ketten *et al.,* 1993; Ketten, 1995). Underwater sound from drilling and support activities is less energetic and has slower rise times, and there is no proof that they can cause serious injury, death, or stranding. However, the association of mass strandings of beaked whales with naval exercises and, in one case, a Lamont-Doherty Earth Observatory seismic survey, has raised the possibility that beaked whales exposed to strong pulsed sounds may be especially susceptible to injury and/or behavioral reactions that can lead to stranding. The potential for stranding to result from exposure to strong pulsed sound suggests that caution be used when exposing marine mammals to pulsed or other underwater sound. Most of the stranding events associated with exposure of marine mammals to pulsed sound however, have involved beaked whales which do not occur in the proposed area. Additionally, the sound produced from the proposed activities will be at much lower levels than those reported during stranding events, as the source levels of the drillship are much lower than those other sources. Pulsed sounds, such as those produced by seismic airgun arrays, are transient and have rapid rise times, whereas the non-impulsive, continuous sounds produced by the drillship to be used by Shell do not have rapid rise time. Rise time is the fluctuation in sound levels of the source. The type of sound that would be produced during the proposed drilling program will be constant and will not exhibit any sudden fluctuations or changes.

The potential effects to marine mammals described in this section of the document do not take into consideration the proposed monitoring

and mitigation measures described later in this document (see the "Proposed Mitigation" and "Proposed Monitoring and Reporting" sections).

Anticipated Effects on Habitat

The primary potential impacts to marine mammals and other marine species are associated with elevated sound levels produced by the exploratory drilling program. However, other potential impacts to the surrounding habitat from physical disturbance are also possible.

Potential Impacts From Seafloor Disturbance

There is a possibility of some seafloor disturbance or temporary increased turbidity in the seabed sediments during anchoring and excavation of the mudline cellars (MLCs). The amount and duration of disturbed or turbid conditions will depend on sediment material and consolidation of specific activity.

Both the anchor and anchor chain will disturb sediments and create an "anchor scar," which is a depression in the seafloor caused by the anchor embedding. The anchor scar is a depression with ridges of displaced sediment, and the area of disturbance will often be greater than the size of the anchor itself because the anchor is dragged along the seafloor until it takes hold and sets. The drilling units will be stabilized and held in place with a system of eight 7,000 kg anchors during operations, which are designed to embed into the seafloor. Each anchor may impact an area of 775 ft^2 (72 m^2) of the seafloor. Minimum impact estimates from each well or mooring by the *Discoverer* is 9,300 ft^2 (864 m^2) of seafloor. This estimate assumes that the anchors are set only once and not moved by outside forces such as sea current. However, based on the vast size of the Beaufort Sea, the area of disturbance is not anticipated to adversely affect marine mammal use of the area.

Once the drillship ends operation, the anchors will be retrieved. Over time, the anchor scars will be filled through natural movement of sediment. The duration of the scars depends upon the energy of the system, water depth, ice scour, and sediment type. Anchor scars were visible under low energy conditions in the North Sea for 5–10 years after retrieval. Scars typically do not form or persist in sandy mud or sand sediments (such as those found in the Beaufort Sea) but may last for 9 years in hard clays (Centaur Associates Inc., 1984). The energy regime plus possible effects of ice gouge in the Beaufort Sea suggest that anchor scars would be refilled faster than in the North Sea.

Vessel mooring and MLC construction would result in increased suspended sediment in the water column that could result in lethal effects on some zooplankton (food source for baleen whales). However, compared to the overall population of zooplankton and the localized nature of effects, any mortality that may occur would not be considered significant. Due to fast regeneration periods of zooplankton, populations are expected to recover quickly.

Impacts on fish resulting from suspended sediments would be dependent upon the life stage of the fish (*e.g.,* eggs, larvae, juveniles, or adults), the concentration of the suspended sediments, the type of sediment, and the duration of exposure (IMG Golder, 2004). Eggs and larvae have been found to exhibit greater sensitivity to suspended sediments (Wilber and Clarke, 2001) and other stresses, which is thought to be related to their relative lack of motility (Auld and Schubel, 1978). Sedimentation could affect fish by causing egg morbidity of demersal fish feeding near or on the ocean floor (Wilber and Clarke, 2001). Surficial membranes are especially susceptible to abrasion (Cairns and Scheier, 1968). However, most of the abundant Beaufort Sea fish species with demersal eggs spawn under the ice in the winter well before MLC excavation would occur. Exposure of pelagic eggs would be much shorter as they move with ocean currents (Wilber and Clarke, 2001).

Suspended sediments, resulting from vessel mooring and MLC excavation, are not expected to result in permanent damage to habitats used by the marine mammal species in the proposed project area or on the food sources that they utilize. Rather, NMFS considers that such impacts will be temporary in nature and concentrated in the areas directly surrounding vessel mooring and MLC excavation activities—areas which are very small relative to the overall Beaufort Sea region.

Potential Impacts From Sound Generation

With regard to fish as a prey source for odontocetes and seals, fish are known to hear and react to sounds and to use sound to communicate (Tavolga *et al.,* 1981) and possibly avoid predators (Wilson and Dill, 2002). Experiments have shown that fish can sense both the strength and direction of sound (Hawkins, 1981). Primary factors determining whether a fish can sense a sound signal, and potentially react to it, are the frequency of the signal and the strength of the signal in relation to the natural background noise level.

The level of sound at which a fish will react or alter its behavior is usually well above the detection level. Fish have been found to react to sounds when the sound level increased to about 20 dB above the detection level of 120 dB (Ona, 1988); however, the response threshold can depend on the time of year and the fish's physiological condition (Engas *et al.,* 1993). In general, fish react more strongly to pulses of sound rather than a continuous signal (Blaxter *et al.,* 1981), such as the type of sound that will be produced by the drillship, and a quicker alarm response is elicited when the sound signal intensity rises rapidly compared to sound rising more slowly to the same level.

Investigations of fish behavior in relation to vessel noise (Olsen *et al.,* 1983; Ona, 1988; Ona and Godo, 1990) have shown that fish react when the sound from the engines and propeller exceeds a certain level. Avoidance reactions have been observed in fish such as cod and herring when vessels approached close enough that received sound levels are 110 dB to 130 dB (Nakken, 1992; Olsen, 1979; Ona and Godo, 1990; Ona and Toresen, 1988). However, other researchers have found that fish such as polar cod, herring, and capeline are often attracted to vessels (apparently by the noise) and swim toward the vessel (Rostad *et al.,* 2006). Typical sound source levels of vessel noise in the audible range for fish are 150 dB to 170 dB (Richardson *et al.,* 1995a). (Based on measurements from the *Northern Explorer II,* the 160 dB radius for the *Discoverer* was modeled by JASCO to be approximately 115 ft [35 m]; therefore, fish would need to be in close proximity to the drillship for the noise to be audible). In calm weather, ambient noise levels in audible parts of the spectrum lie between 60 dB to 100 dB.

Sound will also occur in the marine environment from the various support vessels. Reported source levels for vessels during ice-management have ranged from 175 dB to 185 dB (Brewer *et al.,* 1993, Hall *et al.,* 1994). However, ice-management activities are not expected to be necessary throughout the entire drilling season, so impacts from that activity would occur less frequently than sound from the drillship. Sound pressures generated while drilling have been measured during past exploration in the Beaufort and Chukchi seas. Sounds generated by drilling and ice-management are generally low

frequency and within the frequency range detectable by most fish.

Based on a sound level of approximately 140 dB, there may be some avoidance by fish of the area near the drillship while drilling, around ice-management vessels in transit and during ice-management, and around other support and supply vessels when underway. Any reactions by fish to these sounds will last only minutes (Mitson and Knudsen, 2003; Ona *et al.,* 2007) longer than the vessel is operating at that location or the drillship is drilling. Any potential reactions by fish would be limited to a relatively small area within about 0.21 mi (0.34 km) of the drillship during drilling (JASCO, 2007). Avoidance by some fish or fish species could occur within portions of this area. No important spawning habitats are known to occur at or near the drilling locations. Additionally, impacts to fish as a prey species for odontocetes and seals are expected to be minor.

Some mysticetes, including bowhead whales, feed on concentrations of zooplankton. Some feeding bowhead whales may occur in the Alaskan Beaufort Sea in July and August, and others feed intermittently during their westward migration in September and October (Richardson and Thomson [eds.], 2002; Lowry *et al.,* 2004). Reactions of zooplankton to sound are, for the most part, not known. Their ability to move significant distances is limited or nil, depending on the type of zooplankton. A reaction by zooplankton to sounds produced by the exploratory drilling program would only be relevant to whales if it caused concentrations of zooplankton to scatter. Pressure changes of sufficient magnitude to cause that type of reaction would probably occur only very close to the sound source, if any would occur at all due to the low energy sounds produced by the drillship. Impacts on zooplankton behavior are predicted to be inconsequential. Thus, feeding mysticetes would not be adversely affected by this minimal loss or scattering, if any, of reduced zooplankton abundance.

Aerial surveys in recent years have sighted bowhead whales feeding in Camden Bay on their westward migration through the Beaufort Sea. Individuals feeding in the Camden Bay area at the beginning of the migration (*i.e.,* approximately late August or early September) are not expected to be impacted by Shell's proposed drilling program, primarily because of Shell's proposal to suspend operations and depart the area on August 25 and not return until the close of the Kaktovik and Nuiqsut (Cross Island) hunts, which typically ends around mid- to late September (see the "*Plan of Cooperation (POC)*" subsection later in this document for more details). If other individual bowheads stop to feed in the Camden Bay area after Shell resumes drilling operations in mid- to late September, they may potentially be exposed to sounds from the drillship. However, injury to the bowhead whales is not anticipated, as the source level of the drillship is not loud enough to cause even mild TTS, as discussed earlier in this document. As mentioned earlier in this document, some bowhead whales have demonstrated avoidance behavior in areas of industrial sound (*e.g.,* Richardson *et al.,* 1999) and some have continued to feed even in the presence of industrial activities (Richardson, 2004). However, Camden Bay is one of a few feeding locations for bowhead whales in the Beaufort Sea. Also, as discussed previously, drilling operations are not expected to adversely affect bowhead whale prey species or preclude bowhead whales from obtaining sufficient food resources along their traditional migratory path.

Potential Impacts From Drillship Presence

The *Discoverer* is 514 ft (156.7 m) long. If an animal's swim path is directly perpendicular to the drillship, the animal will need to swim around the ship in order to pass through the area. The length of the drillship (approximately one and a half football fields) is not significant enough to cause a large-scale diversion from the animals' normal swim and migratory paths. Additionally, the eastward spring bowhead whale migration will occur prior to the beginning of Shell's proposed exploratory drilling program. The westward fall bowhead whale migration begins in late August/early September and lasts through October. As discussed throughout this document, Shell plans to suspend all operations on August 25, move the drillship and all support vessels out of the area to a location north and west of the well sites, and will not resume drilling activities until the close of the Kaktovik and Nuiqsut bowhead subsistence hunts. This will reduce the amount of time that the *Discoverer* may impede the bowheads' normal swim and migratory paths as they move through Camden Bay. Moreover, any deflection of bowhead whales or other marine mammal species due to the physical presence of the drillship or its support vessels would be very minor. The drillship's physical footprint is small relative to the size of the geographic region it will occupy and will likely not cause marine mammals to deflect greatly from their typical migratory route. Also, even if animals may deflect because of the presence of the drillship, the Beaufort Sea's migratory corridor is much larger in size than the length of the drillship (many dozens of miles vs. less than two football fields), and animals would have other means of passage around the drillship. In sum, the physical presence of the drillship is not likely to cause a significant deflection to migrating marine mammals.

Potential Impacts From Ice Management

Ice-management activities include the physical pushing or moving of ice to create more open-water in the proposed drilling area and to prevent ice floes from striking the drillship. Ringed, bearded, and spotted seals (along with the ribbon seal and walrus) are dependent on sea ice for at least part of their life history. Sea ice is important for life functions such as resting, breeding, and molting. These species are dependent on two different types of ice: Pack ice and landfast ice. Should ice-management activities be necessary during the proposed drilling program, Shell would only manage pack ice in either early to mid-July or mid- to late October. Landfast ice would not be present during Shell's proposed operations.

The ringed seal is the most common pinniped species in the proposed project area. While ringed seals use ice year-round, they do not construct lairs for pupping until late winter/early spring on the landfast ice. Therefore, since Shell plans to conclude drilling on October 31, Shell's activities would not impact ringed seal lairs or habitat needed for breeding and pupping in the Camden Bay area. Ringed seals can be found on the pack ice surface in the late spring and early summer in the Beaufort Sea, the latter part of which may overlap with the start of Shell's proposed drilling activities. If an ice floe is pushed into one that contains hauled out seals, the animals may become startled and enter the water when the two ice floes collide. Bearded seals breed in the Bering and Chukchi Seas, as the Beaufort Sea provides less suitable habitat for the species. Spotted seals are even less common in the Camden Bay area. This species does not breed in the Beaufort Sea. Therefore, ice used by bearded and spotted seals needed for life functions such as breeding and molting would not be impacted as a result of Shell's drilling program since these life functions do not occur in the proposed project area.

For ringed seals, ice-management would occur during a time when life functions such as breeding, pupping, and molting do not occur in the proposed activity area. Additionally, these life functions normally occur on landfast ice, which will not be impacted by Shell's activity.

In conclusion, NMFS has preliminarily determined that Shell's proposed exploration drilling program in Camden Bay, Beaufort Sea, Alaska, is not expected to have any habitat-related effects that could cause significant or long-term consequences for individual marine mammals or on the food sources that they utilize.

Proposed Mitigation

In order to issue an incidental take authorization (ITA) under Sections 101(a)(5)(A) and (D) of the MMPA, NMFS must, where applicable, set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant).

Mitigation Measures Proposed in Shell's IHA Application

Shell submitted a Marine Mammal Monitoring and Mitigation Plan (4MP) as part of its application (Attachment B; *see* **ADDRESSES**). Shell's planned offshore drilling program incorporates both design features and operational procedures for minimizing potential impacts on marine mammals and on subsistence hunts. The design features and operational procedures have been described in the IHA and LOA applications submitted to NMFS and USFWS, respectively, and are summarized here. Survey design features include:

- Timing and locating drilling and support activities to avoid interference with the annual fall bowhead whale hunts from Kaktovik, Nuiqsut (Cross Island), and Barrow;
- Identifying transit routes and timing to avoid other subsistence use areas and communicating with coastal communities before operating in or passing through these areas; and
- Conducting pre-season sound propagation modeling to establish the appropriate safety and behavioral radii.

Shell indicates that the potential disturbance of marine mammals during operations will be minimized further through the implementation of several ship-based mitigation measures, which include establishing and monitoring safety and disturbance zones and shutting down activities for a portion of the open-water season.

Safety radii for marine mammals around sound sources are customarily defined as the distances within which received sound levels are greater than or equal to 180 dB re 1 µPa (rms) for cetaceans and greater than or equal to 190 dB re 1 µPa (rms) for pinnipeds. These safety criteria are based on an assumption that sounds at lower received levels will not injure these animals or impair their hearing abilities, but that higher received levels might have such effects. It should be understood that marine mammals inside these safety zones will not necessarily be injured, seriously injured, or killed, as the received sound thresholds which determine these zones were established prior to the current understanding that significantly higher levels of sound would be required before injury, serious injury, or mortality could occur (*see* Southall *et al.,* 2007). With respect to Level B harassment, NMFS' practice has been to apply the 120 dB re 1 µPa (rms) received level threshold for underwater continuous sound levels.

Initial safety and behavioral radii for the sound levels produced by the drilling activities have been modeled. These radii will be used for mitigation purposes, should they be necessary, until direct measurements are available early during the exploration activities. However, it is not anticipated that source levels from the *Discoverer* will reach the 180- or 190-dB (rms) levels.

Sounds from the *Discoverer* have not previously been measured in the Arctic or elsewhere, but sounds from a similar drillship, *Explorer II,* were measured in the Beaufort Sea (Greene, 1987; Miles *et al.,* 1987). The underwater received SPL in the 20 to 1,000 Hz band for drilling activity by the *Explorer II,* including a nearby support vessel, was 134 dB re 1 µPa (rms) at 0.1 mi (0.2 km; Greene 1987). The back-propagated source levels (175 dB re 1 µPa at 1 m) from these measurements were used as a proxy for modeling the sounds likely to be produced by drilling activities from the *Discoverer.* Based on the models, source levels from drilling are not expected to reach the 180 dB rms level and are expected to fall below 160 dB rms at 115 ft (35 m) from the drillship. The 120 dB rms radius is expected to be 3 mi (4.9 km) from the drillship. These estimated source measurements were used to model the expected sounds produced at the exploratory well sites by the *Discoverer.*

Based on the best available scientific literature, the source levels noted above for exploration drilling are not high enough to cause a temporary reduction in hearing sensitivity or permanent hearing damage to marine mammals. Consequently, Shell believes that mitigation as described for seismic activities including ramp ups, power downs, and shutdowns should not be necessary for drilling activities. NMFS has also preliminarily determined that these types of mitigation measures, traditionally required for seismic survey operations, are not practical or necessary for this proposed drilling activity. Seismic airgun arrays can be turned on slowly (*i.e.,* only turning on one or some guns at a time) and powered down quickly. The types of sound sources used for exploratory drilling have different properties and are unable to be "powered down" like airgun arrays or shutdown instantaneously without posing other risks. However, Shell plans to use marine mammal observers (MMOs) onboard the drillship and the various support vessels to monitor marine mammals and their responses to industry activities and to initiate mitigation measures should in-field measurements of the operations indicate that such measures are necessary. Additional details on the MMO program are described in the "Proposed Monitoring and Reporting" section found later in this document.

Drilling sounds are expected to vary significantly with time due to variations in the level of operations and the different types of equipment used at different times onboard the drillship. Once on location in Camden Bay, Shell will conduct sound source verification (SSV) tests to establish safety zones for the previously mentioned sound level criteria. The objectives of the SSV tests are: (1) To quantify the absolute sound levels produced by drilling and to monitor their variations with time, distance, and direction from the drillship; and (2) to measure the sound levels produced by vessels operating in support of drilling operations, which include crew change vessels, tugs, ice-management vessels, and spill response vessels. The methodology for conducting the SSV tests is fully described in Shell's 4MP (*see* **ADDRESSES**). Please refer to that document for further details. Upon completion of the SSV tests, the new radii will be established and monitored, and mitigation measures will be implemented in accordance with Shell's 4MP.

Additional mitigation measures proposed by Shell include: (1) Reducing speed and/or changing course if a marine mammal is sighted from a vessel in transit (NMFS has proposed a

specific distance in the next subsection); (2) resuming full activity (*e.g.,* full support vessel speed) only after marine mammals are confirmed to be outside the safety zone; (3) implementing flight restrictions prohibiting aircraft from flying below 1,500 ft (457 m) altitude (except during takeoffs and landings or in emergency situations); and (4) keeping vessels anchored when approached by marine mammals to avoid the potential for avoidance reactions by such animals.

Shell has also proposed additional mitigation measures to ensure no unmitigable adverse impact on the availability of affected species or stocks for taking for subsistence uses. Those measures are described in the "Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses" section found later in this document.

Additional Mitigation Measures Proposed by NMFS

In addition to the mitigation measures proposed in Shell's IHA application, NMFS proposes the following measures be included in the IHA, if issued, in order to ensure the least practicable impact on the affected species or stocks:

(1) All vessels should reduce speed when within 300 yards (274 m) of whales. The reduction in speed will vary based on the situation but must be sufficient to avoid interfering with the whales. Those vessels capable of steering around such groups should do so. Vessels may not be operated in such a way as to separate members of a group of whales from other members of the group;

(2) Avoid multiple changes in direction and speed when within 300 yards (274 m) of whales; and

(3) When weather conditions require, such as when visibility drops, support vessels must reduce speed and change direction, as necessary (and as operationally practicable), to avoid the likelihood of injury to whales.

Mitigation Conclusions

NMFS has carefully evaluated the applicant's proposed mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must, where applicable, set forth "requirements pertaining to the monitoring and reporting of such taking". The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

Monitoring Measures Proposed in Shell's IHA Application

The monitoring plan proposed by Shell can be found in the 4MP (Attachment B of Shell's application; *see* **ADDRESSES**). The plan may be modified or supplemented based on comments or new information received from the public during the public comment period or from the peer review panel (*see* the "Monitoring Plan Peer Review" section later in this document). A summary of the primary components of the plan follows.

(1) Vessel-Based MMOs

Vessel-based monitoring for marine mammals will be done by trained MMOs throughout the period of drilling operations. MMOs will monitor the occurrence and behavior of marine mammals near the drillship during all daylight periods during operation and during most daylight periods when drilling operations are not occurring. MMO duties will include watching for and identifying marine mammals, recording their numbers, distances, and reactions to the drilling operations. A sufficient number of MMOs will be required onboard each vessel to meeting the following criteria: (1) 100 percent monitoring coverage during all periods of drilling operations in daylight; (2) maximum of 4 consecutive hours on watch per MMO; and (3) maximum of 12 hours of watch time per day per MMO. Shell anticipates that there will be provision for crew rotation at least every 6 weeks to avoid observer fatigue.

Biologist-observers will have previous marine mammal observation experience, and field crew leaders will be highly experienced with previous vessel-based marine mammal monitoring projects. Resumes for those individuals will be provided to NMFS so that NMFS can review and accept their qualifications. Inupiat observers will be experienced in the region, familiar with the marine mammals of the area, and complete a NMFS approved observer training course designed to familiarize individuals with monitoring and data collection procedures. A MMO handbook, adapted for the specifics of the planned Shell drilling program, will be prepared and distributed beforehand to all MMOs.

MMOs will watch for marine mammals from the best available vantage point on the drillship and support vessels. MMOs will scan systematically with the unaided eye and 7 x 50 reticle binoculars, supplemented with 20 x 60 image-stabilized Zeiss Binoculars or Fujinon 25 x 150 "Big-eye" binoculars and night-vision equipment when needed. Personnel on the bridge will assist the MMOs in watching for marine mammals.

Information to be recorded by marine mammal observers will include the same types of information that were recorded during recent monitoring programs associated with industry activity in the Arctic (*e.g.,* Ireland *et al.,* 2009). When a mammal sighting is made, the following information about the sighting will be recorded:

(A) Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), bearing and distance from the MMO, apparent reaction to activities (*e.g.,* none, avoidance, approach, paralleling, *etc.*), closest point of approach, and behavioral pace;

(B) Time, location, speed, activity of the vessel, sea state, ice cover, visibility, and sun glare; and

(C) The positions of other vessel(s) in the vicinity of the MMO location.

The ship's position, speed of support vessels, and water temperature, water depth, sea state, ice cover, visibility, and sun glare will also be recorded at the start and end of each observation watch, every 30 minutes during a watch, and whenever there is a change in any of those variables.

Distances to nearby marine mammals will be estimated with binoculars (Fujinon 7 x 50 binoculars) containing a reticle to measure the vertical angle of the line of sight to the animal relative to the horizon. MMOs may use a laser rangefinder to test and improve their abilities for visually estimating distances to objects in the water. However, previous experience showed that a Class 1 eye-safe device was not able to measure distances to seals more than about 230 ft (70 m) away. The device was very useful in improving the distance estimation abilities of the observers at distances up to about 1968 ft (600 m)—the maximum range at which the device could measure distances to highly reflective objects such as other vessels. Humans observing objects of more-or-less known size via a standard observation protocol, in this case from a standard height above water, quickly become able to estimate distances within about ±20 percent when given immediate feedback about actual distances during training.

(2) Aerial Survey Program

Shell proposes to conduct an aerial survey program in support of the drilling program in the Beaufort Sea during the summer and fall of 2010. Shell's objectives for this program include:

(A) To advise operating vessels as to the presence of marine mammals (primarily cetaceans) in the general area of operation;

(B) To collect and report data on the distribution, numbers, movement and behavior of marine mammals near the drilling operations with special emphasis on migrating bowhead whales;

(C) To support regulatory reporting related to the estimation of impacts of drilling operations on marine mammals;

(D) To investigate potential deflection of bowhead whales during migration by documenting how far east of drilling operations a deflection may occur and where whales return to normal migration patterns west of the operations; and

(E) To monitor the accessibility of bowhead whales to Inupiat hunters.

Aerial survey flights will begin 5 to 7 days before operations at the exploration well sites get underway. Surveys will be flown daily throughout drilling operations, weather and flight conditions permitting, and continued for 5 to 7 days after all activities at the site have ended.

The aerial survey procedures will be generally consistent with those used during earlier industry studies (Davis *et al.,* 1985; Johnson *et al.,* 1986; Evans *et al.,* 1987; Miller *et al.,* 1997, 1998, 1999, 2002; Patterson, 2007). This will facilitate comparison and pooling of data where appropriate. However, the specific survey grids will be tailored to Shell's operations. During the 2010 drilling season Shell will coordinate and cooperate with the aerial surveys conducted by MMS/NMFS and any other groups conducting surveys in the same region.

For marine mammal monitoring flights, aircraft will be flown at approximately 120 knots (138 mph) ground speed and usually at an altitude of 1,000 ft (305 m). Surveys in the Beaufort Sea are directed at bowhead whales, and an altitude of 900–1,000 ft (274–305 m) is the lowest survey altitude that can normally be flown without concern about potential aircraft disturbance. Aerial surveys at an altitude of 1,000 ft (305 m) do not provide much information about seals but are suitable for both bowhead and beluga whales. The need for a 900–1000+ (374–305 m) ft cloud ceiling will limit the dates and times when surveys can be flown.

Two primary observers will be seated at bubble windows on either side of the aircraft and a third observer will observe part time and record data the rest of the time. All observers need bubble windows to facilitate downward viewing. For each marine mammal sighting, the observer will dictate the species, number, size/age/sex class when determinable, activity, heading, swimming speed category (if traveling), sighting cue, ice conditions (type and percentage), and inclinometer reading to the marine mammal into a digital recorder. The inclinometer reading will be taken when the animal's location is 90° to the side of the aircraft track, allowing calculation of lateral distance from the aircraft trackline.

Transect information, sighting data and environmental data will be entered into a GPS-linked computer by the third observer and simultaneously recorded on digital voice recorders for backup and validation. At the start of each transect, the observer recording data will record the transect start time and position, ceiling height (ft), cloud cover (in 10ths), wind speed (knots), wind direction (°T) and outside air temperature (°C). In addition, each observer will record the time, visibility (subjectively classified as excellent, good, moderately impaired, seriously impaired or impossible), sea state (Beaufort wind force), ice cover (in 10ths) and sun glare (none, moderate, severe) at the start and end of each transect, and at 2 min intervals along the transect. The data logger will automatically record time and aircraft position (latitude and longitude) for sightings and transect waypoints, and at pre-selected intervals along the transects. Ice observations during aerial surveys will be recorded and satellite imagery may be used, where available, during post-season analysis to determine ice conditions adjacent to the survey area. These are standard practices for surveys of this type and are necessary in order to interpret factors responsible for variations in sighting rates.

During the late summer and fall, the bowhead whale is the primary species of concern, but belugas and gray whales are also present. To address concerns regarding deflection of bowheads at greater distances, the survey pattern around drilling operations has been designed to document whale distribution from about 25 mi (40 km) east of the drilling operations to about 37 mi (60 km) west of operations (*see* Figure 1 of Shell's 4MP).

Bowhead whale movements during the late summer/autumn are generally from east to west, and transects should be designed to intercept rather than parallel whale movements. The transect lines in the grid will be oriented north-south, equally spaced at 5 mi (8 km) and randomly shifted in the east-west direction for each survey by no more than the transect spacing. The survey grid will total about 808 mi (1,300 km) in length, requiring approximately 6 hours to survey at a speed of 120 knots (138 mph), plus ferry time. Exact lengths and durations will vary somewhat depending on the position of the drilling operation and thus of the grid, the sequence in which lines are flown (often affected by weather), and the number of refueling/rest stops.

Weather permitting, transects making up the grid in the Beaufort Sea will be flown in sequence from west to east. This decreases difficulties associated with double counting of whales that are (predominantly) migrating westward. The survey sequence around the drilling operation is designed to monitor the distribution of whales around the drilling operation.

(3) Acoustic Monitoring

As discussed earlier in this document, Shell will conduct SSV tests to establish the isopleths for the applicable safety radii. In addition, Shell proposes to use acoustic recorders to study bowhead deflections.

Shell plans to deploy arrays of acoustic recorders in the Beaufort Sea in 2010, similar to that which was done in 2007 and 2008 using Directional Autonomous Seafloor Acoustic Recorders (DASARs). These directional

acoustic systems permit localization of bowhead whale and other marine mammal vocalizations. The purpose of the array will be to further understand, define, and document sound characteristics and propagation resulting from vessel-based drilling operations that may have the potential to cause deflections of bowhead whales from their migratory pathway. Of particular interest will be the east-west extent of deflection, if any (i.e., how far east of a sound source do bowheads begin to deflect and how far to the west beyond the sound source does deflection persist). Of additional interest will be the extent of offshore (or towards shore) deflection that might occur.

In previous work around seismic and drillship operations in the Alaskan Beaufort Sea, the primary method for studying this question has been aerial surveys. Acoustic localization methods will provide supplementary information for addressing the whale deflection question. Compared to aerial surveys, acoustic methods have the advantage of providing a vastly larger number of whale detections, and can operate day or night, independent of visibility, and to some degree independent of ice conditions and sea state—all of which prevent or impair aerial surveys. However, acoustic methods depend on the animals to call, and to some extent, assume that calling rate is unaffected by exposure to industrial noise. Bowheads call frequently in fall, but there is some evidence that their calling rate may be reduced upon exposure to industrial sounds, complicating interpretation. The combined use of acoustic and aerial survey methods will provide a suite of information that should be useful in assessing the potential effects of drilling operations on migrating bowhead whales.

Using passive acoustics with directional autonomous recorders, the locations of calling whales will be observed for a 6- to 10-week continuous monitoring period at five coastal sites (subject to favorable ice and weather conditions). Essential to achieving this objective is the continuous measurement of sound levels near the drillship.

Shell plans to conduct the whale migration monitoring using the passive acoustics techniques developed and used successfully since 2001 for monitoring the migration past Northstar production island northwest of Prudhoe Bay and from Kaktovik to Harrison Bay during the 2007 and 2008 migrations. Those techniques involve using DASARs to measure the arrival angles of bowhead calls at known locations, then triangulating to locate the calling whale.

In attempting to assess the responses of bowhead whales to the planned industrial operations, it will be essential to monitor whale locations at sites both near and far from industry activities. Shell plans to monitor at five sites along the Alaskan Beaufort coast as shown in Figure 10 of Shell's 4MP. The eastern-most site (#5 in Figure 10 of the 4MP) will be just east of Kaktovik (approximately 62 mi [100 km] west of the Sivulliq drilling area) and the western-most site (#1 in Figure 10 of the 4MP) will be in the vicinity of Harrison Bay (approximately 109 mi [175 km] west of Sivulliq) . Site 2 will be located west of Prudhoe Bay (approximately 68 mi [110 km] west of Sivulliq). Site 4 will be approximately 6.2 mi (10 km) east of the Sivulliq drilling area, and site 3 will be approximately 15.5 mi (25 km) west of Sivulliq. These five sites will provide information on possible migration deflection well in advance of whales encountering an industry operation and on "recovery" after passing such operations should a deflection occur.

The proposed geometry of DASARs at each site is comprised of seven DASARs oriented in a north-south pattern so that five equilateral triangles with 4.3-mi (7-km) element spacing is achieved. DASARs will be installed at planned locations using a GPS. However, each DASAR's orientation once it settles on the bottom is unknown and must be determined to know how to reference the call angles measured to the whales. Also, the internal clocks used to sample the acoustic data typically drift slightly, but linearly, by an amount up to a few seconds after 6 weeks of autonomous operation. Knowing the time differences within a second or two between DASARs is essential for identifying identical whale calls received on two or more DASARs.

Bowhead migration begins in late August with the whales moving westward from their feeding sites in the Canadian Beaufort Sea. It continues through September and well into October. However, because of the drilling schedule, Shell will attempt to install the 21 DASARs at three sites (3, 4 and 5) in early August. The remaining 14 DASARs will be installed at sites 1 and 2 in late August. Thus, Shell proposes to be monitoring for whale calls from before August 15 until sometime before October 15.

At the end of the season, the fourth DASAR in each array will be refurbished, recalibrated, and redeployed to collect data through the winter. The other DASARs in the arrays will be recovered. The redeployed DASARs will be programmed to record 35 min every 3 hours with a disk capacity of 10 months at that recording rate. This should be ample space to allow over-wintering from approximately mid-October 2010, through mid-July 2011.

Additional details on methodology and data analysis for the three types of monitoring described here (*i.e.,* vessel-based, aerial, and acoustic) can be found in the 4MP in Shell's application (*see* **ADDRESSES**).

Monitoring Plan Peer Review

The MMPA requires that monitoring plans be independently peer reviewed "where the proposed activity may affect the availability of a species or stock for taking for subsistence uses" (16 U.S.C. 1371(a)(5)(D)(ii)(III)). Regarding this requirement, NMFS' implementing regulations state, "Upon receipt of a complete monitoring plan, and at its discretion, [NMFS] will either submit the plan to members of a peer review panel for review or within 60 days of receipt of the proposed monitoring plan, schedule a workshop to review the plan" (50 CFR 216.108(d)).

NMFS has established an independent peer review panel to review Shell's 4MP for Exploration Drilling of Selected Lease Areas in the Alaskan Beaufort Sea in 2010. The panel met in late March 2010, and will provide comments to NMFS in mid-April 2010. After completion of the peer review, NMFS will consider all recommendations made by the panel, incorporate appropriate changes into the monitoring requirements of the IHA (if issued), and publish the panel's findings and recommendations in the final IHA notice of issuance or denial document.

Reporting Measures

(1) SSV Report

A report on the preliminary results of the acoustic verification measurements, including as a minimum the measured 190-, 180-, 160-, and 120-dB (rms) radii of the drillship and the support vessels, will be submitted within 120 hr after collection and analysis of those measurements at the start of the field season. This report will specify the distances of the safety zones that were adopted for the exploratory drilling program.

(2) Technical Reports

The results of Shell's 2010 Camden Bay exploratory drilling monitoring program (i.e., vessel-based, aerial, and acoustic) will be presented in the "90-day" and Final Technical reports, as required by NMFS under IHAs. Shell proposes that the Technical Reports will include: (1) Summaries of monitoring

effort (*e.g.,* total hours, total distances, and marine mammal distribution through study period, accounting for sea state and other factors affecting visibility and detectability of marine mammals); (2) analyses of the effects of various factors influencing detectability of marine mammals (*e.g.,* sea state, number of observers, and fog/glare); (3) species composition, occurrence, and distribution of marine mammal sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, and ice cover; (4) sighting rates of marine mammals during periods with and without drilling activities (and other variables that could affect detectability); (5) initial sighting distances versus drilling state; (6) closest point of approach versus drilling state; (7) observed behaviors and types of movements versus drilling state; (8) numbers of sightings/individuals seen versus drilling state; (9) distribution around the drillship and support vessels versus drilling state; and (10) estimates of take by harassment. This information will be reported for both the vessel-based and aerial monitoring.

Analysis of all acoustic data will be prioritized to address the primary questions, which are to: (a) Determine when, where, and what species of animals are acoustically detected on each DASAR; (b) analyze data as a whole to determine offshore bowhead distributions as a function of time; (c) quantify spatial and temporal variability in the ambient noise; and (d) measure received levels of drillship activities. The bowhead detection data will be used to develop spatial and temporal animal distributions. Statistical analyses will be used to test for changes in animal detections and distributions as a function of different variables (*e.g.,* time of day, time of season, environmental conditions, ambient noise, vessel type, operation conditions).

The initial technical report is due to NMFS within 90 days of the completion of Shell's Beaufort Sea exploratory drilling program. The "90-day" report will be subject to review and comment by NMFS. Any recommendations made by NMFS must be addressed in the final report prior to acceptance by NMFS.

(3) Comprehensive Report

In November, 2007, Shell (in coordination and cooperation with other Arctic seismic IHA holders) released a final, peer-reviewed edition of the 2006 Joint Monitoring Program in the Chukchi and Beaufort Seas, July–November 2006 (LGL, 2007). This report is available on the NMFS Protected Resources Web site (*see* **ADDRESSES**). In March, 2009, Shell released a final, peer-reviewed edition of the Joint Monitoring Program in the Chukchi and Beaufort Seas, Open Water Seasons, 2006–2007 (Ireland *et al.,* 2009). This report is also available on the NMFS Protected Resources Web site (*see* **ADDRESSES**). A draft comprehensive report for 2008 (Funk *et al.,* 2009) was provided to NMFS and those attending the Arctic Stakeholder Open-water Workshop in Anchorage, Alaska, on April 6–8, 2009. The 2008 report provides data and analyses from a number of industry monitoring and research studies carried out in the Chukchi and Beaufort Seas during the 2008 open-water season with comparison to data collected in 2006 and 2007. Reviewers plan to provide comments on the 2008 report to Shell. Once Shell is able to incorporate reviewer comments, the final 2008 report will be made available to the public. The 2009 draft comprehensive report is due to NMFS by mid-April 2010. NMFS will make this report available to the public upon receipt.

Following the 2010 drilling season a comprehensive report describing the vessel-based, aerial, and acoustic monitoring programs will be prepared. The comprehensive report will describe the methods, results, conclusions and limitations of each of the individual data sets in detail. The report will also integrate (to the extent possible) the studies into a broad based assessment of industry activities, and other activities that occur in the Beaufort and/or Chukchi seas, and their impacts on marine mammals during 2010. The report will help to establish long-term data sets that can assist with the evaluation of changes in the Chukchi and Beaufort Sea ecosystems. The report will attempt to provide a regional synthesis of available data on industry activity in offshore areas of northern Alaska that may influence marine mammal density, distribution and behavior. The comprehensive report will be due to NMFS within 240 days of the date of issuance of the IHA (if issued).

(4) Notification of Injured or Dead Marine Mammals

Shell will notify NMFS' Office of Protected Resources and NMFS' Stranding Network within 48 hours of sighting an injured or dead marine mammal in the vicinity of drilling operations. Shell will provide NMFS with the species or description of the animal(s), the condition of the animal(s) (including carcass condition if the animal is dead), location, time of first discovery, observed behaviors (if alive), and photo or video (if available).

In the event that an injured or dead marine mammal is found by Shell that is not in the vicinity of the proposed drilling program, Shell will report the same information listed above to NMFS as soon as operationally feasible.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]. Only take by Level B behavioral harassment is anticipated as a result of the proposed drilling program. Anticipated impacts to marine mammals are associated with noise propagation from the drillship and associated support vessels. Additional disturbance to marine mammals may result from aircraft overflights and visual disturbance of the drillship or support vessels. However, based on the flight paths and altitude, impacts from aircraft operations are anticipated to be localized and minimal in nature.

The full suite of potential impacts to marine mammals from various industrial activities was described in detail in the "Potential Effects of the Specified Activity on Marine Mammals" section found earlier in this document. The potential effects of sound from the proposed exploratory drilling program might include one or more of the following: tolerance; masking of natural sounds; behavioral disturbance; non-auditory physical effects; and, at least in theory, temporary or permanent hearing impairment (Richardson *et al.,* 1995a). As discussed earlier in this document, the most common impact will likely be from behavioral disturbance, including avoidance of the ensonified area or changes in speed, direction, and/or diving profile of the animal. For reasons discussed previously in this document, hearing impairment (TTS and PTS) are highly unlikely to occur based on the fact that most of the equipment to be used during Shell's proposed drilling program does not have source levels high enough to elicit even mild TTS. Additionally, non-auditory physiological effects are anticipated to be minor, if any would occur at all. Finally, based on the proposed

mitigation and monitoring measures described earlier in this document and the fact that the back-propagated source level for the drillship is estimated to be 175 dB re 1 μPa (rms), no injury or mortality of marine mammals is anticipated as a result of Shell's proposed exploratory drilling program.

For continuous sounds, such as those produced by drilling operations, NMFS uses a received level of 120-dB (rms) to indicate the onset of Level B harassment. Shell provided calculations for the 120-dB isopleths produced by the *Discoverer* and then used those isopleths to estimate takes by harassment. Shell also included modeling results of the 160-dB isopleths for the *Discoverer* and associated estimated takes by harassment. However, NMFS has used the 120-dB calculations to make the necessary MMPA preliminary findings. Shell provides a full description of the methodology used to estimate takes by harassment in its IHA application (see **ADDRESSES**), which is also provided in the following sections. However, this document only discusses the take estimates at the 120 dB level. Please refer to Shell's application for the full explanation and estimates at the 160 dB level.

Shell has requested authorization for bowhead, gray, and beluga whales and ringed, spotted, and bearded seals. Additionally, Shell provided exposure estimates and requested takes of ribbon seals, humpback whales, minke whales, harbor porpoise, and narwhal. However, as stated previously in this document, sightings of these species are rare, and the likelihood of occurrence of these species in the proposed drilling area is minimal.

Basis for Estimating "Take by Harassment"

"Take by Harassment" is described in this section and was calculated in Shell's application by multiplying the expected densities of marine mammals that may occur near the exploratory drilling operations by the area of water likely to be exposed to continuous sound levels of ≥120 dB. The single exception to this method is for the estimation of exposures of bowhead whales during the fall migration where more detailed data were available, allowing an alternate approach, described below, to be used. NMFS evaluated and critiqued the methods provided in Shell's application and determined that they were appropriate in order to make the necessary preliminary MMPA findings. This section describes the estimated densities of marine mammals that may occur in the project area. The area of water that may be ensonified to the above sound levels is described further in the "*Potential Number of Takes by Harassment*" subsection.

Marine mammal densities near the operation are likely to vary by season and habitat. However, sufficient published data allowing the estimation of separate densities during summer (July and August) and fall (September and October) are only available for beluga and bowhead whales. As noted above, exposures of bowhead whales during the fall are not calculated using densities (see below). Therefore, summer and fall densities have been estimated for beluga whales, and a summer density has been estimated for bowhead whales. Densities of all other species have been estimated to represent the duration of both seasons.

Marine mammal densities are also likely to vary by habitat type. In the Alaskan Beaufort Sea, where the continental shelf break is relatively close to shore, marine mammal habitat is often defined by water depth. Bowhead and beluga occurrence within nearshore (0–131 ft, 0–40 m), outer continental shelf (131–656 ft, 40–200 m), slope (656–6,562 ft, 200–2000 m), basin (>6,562 ft, 2000 m), or similarly defined habitats have been described previously (Moore *et al.,* 2000; Richardson and Thomson, 2002). The presence of most other species has generally only been described relative to the entire continental shelf zone (0–656 ft, 0–200 m) or beyond. Sounds produced by the drilling vessel are expected to drop below 120 dB within the nearshore zone (0–131 ft, 0–40 m, water depth) while sounds produced by ice-management activities, if they are necessary, are likely to also be present in the outer continental shelf (131–656 ft, 40–200 m). Sounds ≥120 dB are not expected to occur in waters >656 ft (200 m). Since the only instance in which sounds at the indicated levels may be introduced to the outer continental shelf would be during ice-management activities, and therefore ice-margin densities are more applicable, separate beluga and bowhead densities for the outer continental shelf have not been used in the calculations.

In addition to water depth, densities of marine mammals are likely to vary with the presence or absence of sea ice (see later for descriptions by species). At times during either summer or fall, pack-ice may be present in some of the area around the drilling operation. However, the retreat of sea ice in the Alaskan Beaufort Sea has been substantial in recent years, so Shell has assumed that only 33 percent of the area exposed to sounds ≥120 dB by the drilling vessel will be in ice margin habitat. Therefore, ice-margin densities of marine mammals in both seasons have been multiplied by 33 percent of the area exposed to sounds by the drilling vessel, while open-water (nearshore) densities have been multiplied by the remaining 67 percent of the area.

To provide some allowance for the uncertainties, "maximum estimates" as well as "average estimates" of the numbers of marine mammals potentially affected have been derived. For a few marine mammal species, several density estimates were available, and in those cases the mean and maximum estimates were determined from the survey data. In other cases, no applicable estimate (or perhaps a single estimate) was available, so correction factors were used to arrive at "average" and "maximum" estimates. These are described in detail in the following subsections. NMFS has determined that the average density data of marine mammal populations will be used to calculate estimated take numbers because these numbers are based on surveys and monitoring of marine mammals in the vicinity of the proposed project area. NMFS only used the "maximum" estimate for marine mammal species that are less likely to occur in the project area and for which little to no density information exists *(i.e.,* gray whales and spotted seals).

Detectability bias, quantified in part by $f(0)$, is associated with diminishing sightability with increasing lateral distance from the trackline. Availability bias [$g(0)$] refers to the fact that there is <100 percent probability of sighting an animal that is present along the survey trackline. Some sources of densities used below included these correction factors in their reported densities. In other cases the best available correction factors were applied to reported results when they had not been included in the reported data (*e.g.,* Moore *et al.,* 2000).

(1) Cetaceans

As noted above, the densities of beluga and bowhead whales present in the Beaufort Sea are expected to vary by season and location. During the early and mid-summer, most belugas and bowheads are found in the Canadian Beaufort Sea and Amundsen Gulf or adjacent areas. Low numbers are found in the eastern Alaskan Beaufort Sea. Belugas begin to move across the Alaskan Beaufort Sea in August, and bowheads do so toward the end of August.

Beluga Whales—Beluga density estimates were derived from data in

Moore *et al.* (2000). During the summer, beluga whales are most likely to be encountered in offshore waters of the eastern Alaskan Beaufort Sea or areas with pack ice. The summer beluga whale nearshore density (Table 6–1 in Shell's application and Table 1 here) was based on 7,447 mi (11,985 km) of on-transect effort and nine associated sightings that occurred in water ≤164 ft (50 m) in Moore *et al.* (2000; Table 6–2 in Shell's application and Table 2 here). A mean group size of 1.63, a *f*(0) value of 2.841, and a *g*(0) value of 0.58 from Harwood *et al.* (1996) were also used in the calculation. Moore *et al.* (2000) found that belugas were equally likely to occur in heavy ice conditions as open-water or very light ice conditions in summer in the Beaufort Sea, so the same density was used for both nearshore and ice-margin estimates (Table 6–1 in Shell's application and Table 1 here). The fall beluga whale nearshore density was based on 45,180.5 mi (72,711 km) of on-transect effort and 28 associated sightings that occurred in water ≤164 ft (50 m) reported in Moore *et al.* (2000). A mean group size of 2.9 (CV=1.9), calculated from all Beaufort Sea fall beluga sightings in ≤164 ft (50 m) of water present in the Bowhead Whale Aerial Survey Program database, along with the same *f*(0) and *g*(0) values from Harwood *et al.* (1996) were also used in the calculation. Moore *et al.* (2000) found that during the fall in the Beaufort Sea belugas occurred in moderate to heavy ice at higher rates than in light ice, so ice-margin densities were estimated to be twice the nearshore densities. Based on the CV of group size maximum estimates in both season and habitats were estimated as four times the average estimates. "Takes by harassment" of beluga whales during the fall in the Beaufort Sea were not calculated in the same manner as described for bowhead whales because of the relatively lower expected densities of beluga whales in nearshore habitat near the exploration drilling program and the lack of detailed data on the likely timing and rate of migration through the area.

TABLE 1—EXPECTED SUMMER (JUL–AUG) DENSITIES OF BELUGA AND BOWHEAD WHALES IN THE EASTERN ALASKAN BEAUFORT SEA. DENSITIES ARE CORRECTED FOR F(0) AND G(0) BIASES. SPECIES LISTED UNDER THE U.S. ESA AS ENDANGERED ARE SHOWN IN ITALIC

Species	Nearshore		Ice margin	
	Average density (# /km^2)	Maximum density (# /km^2)	Average density (# /km^2)	Maximum density (# /km^2)
Beluga	0.0030	0.0120	0.0030	0.0120
Bowhead whale	0.0186	0.0717	0.0186	0.0717

TABLE 2—EXPECTED FALL (SEP–NOV) DENSITIES OF BELUGA AND BOWHEAD WHALES IN THE EASTERN ALASKAN BEAUFORT SEA. DENSITIES ARE CORRECTED FOR F(0) AND G(0) BIASES. SPECIES LISTED UNDER THE U.S. ESA AS ENDANGERED ARE SHOWN IN ITALIC

Species	Nearshore		Ice margin	
	Average density (# /km^2)	Maximum density (# /km^2)	Average density (# /km^2)	Maximum density (# /km^2)
Beluga	0.0027	0.0108	0.0054	0.0216
Bowhead whale[a]	*NA*	*NA*	*NA*	*NA*

[a] See text for description of how bowhead whales estimates were made.

Bowhead Whales—Industry aerial surveys of the continental shelf near Camden Bay in 2008 recorded eastward migrating bowhead whales until July 12 (Lyons and Christie, 2009). No bowhead sightings were recorded again, despite continued flights until August 19. Aerial surveys by industry operators did not begin until late August of 2006 and 2007, but in both years bowheads were also recorded in the region before the end of August (Christie *et al.,* 2009). The late August sightings were likely of bowheads beginning their fall migration, so the densities calculated from those surveys were not used to estimate summer densities in this region. The three surveys in July 2008, resulted in density estimates of 0.0099, 0.0717, and 0.0186 whales/km^2, respectively. The estimate of 0.0186 whales/km^2 was used as the average summer nearshore density, and the estimate of 0.0717 whales/km^2 was used as the maximum. Sea ice was not present during these surveys. Moore *et al.* (2000) reported that bowhead whales in the Alaskan Beaufort Sea were distributed uniformly relative to sea ice, so the same nearshore densities were used for ice-margin habitat.

During the fall, most bowhead whales will be migrating west past the exploration drilling program, so it is less accurate to assume that the number of individuals present in the area from one day to the next will be static. However, feeding, resting, and milling behaviors are not entirely uncommon at this time and location either. In order to incorporate the movement of whales past the planned operations, and because the necessary data are available, Shell developed an alternate method of calculating the number of individual bowheads exposed to sounds produced by the exploration drilling program from the method used to calculate the number of exposures for bowheads in summer and the other marine mammal species for the entire season. The method is founded on estimates of the proportion of the population that would pass within the ≥120 dB zone on a given day in the fall during the exploration drilling program. Based on the fact that most bowhead whales will be engaged in the fall migration at this time, NMFS preliminarily determined that this method was appropriate for estimating the number of individual bowhead whales that may be exposed to drilling sounds after August 25.

Exploration drilling will be suspended on August 25 prior to the start of the bowhead subsistence hunts

at Kaktovik and Nuiqsut (Cross Island) and will be resumed when the hunts are concluded. After the completion of the subsistence hunts (expected in mid-September), approximately 40 days of activity will be required to complete the planned drilling operations. The current population size would be approximately 14,247 individuals based on a 2001 population of 10,545 (Zeh and Punt, 2005) and a continued annual growth rate of 3.4 percent (Allen and Angliss, 2010). Based on data in Richardson and Thomson (2002, Appendix 9.1), the number of whales expected to pass each day after conclusion of the bowhead subsistence hunts (assumed to be September 15) was estimated as a proportion of the population. Minimum and maximum estimates of the number of whales passing each day were not available, so a single estimate based on the 10-day moving average presented by Richardson and Thomson (2002) was used. Richardson and Thomson (2002) also calculated the proportion of animals within water depth bins (<66 ft [20m], 66–131 ft [20–40m], 131–656 ft [40–200m], and >656 ft [200m]). Using this information, Shell multiplied the total number of whales expected to pass the drilling program each day by the proportion of whales that would be in each depth category to estimate how many individuals would be within each depth bin on a given day. The proportion of each depth bin falling within the ≥120 dB zone was then multiplied by the number of whales within the respective bins to estimate the total number of individuals that would be exposed on each day. This was repeated for a total of 40 days (September 15 to October 24), and the results were summed to estimate the total number of bowhead whales that might be exposed to ≥120 dB during the migration period in the Beaufort Sea. If the hunts at Kaktovik and Cross Island (Nuiqsut) end later than September 15, the number of exposures calculated by Shell would be an overestimate, as Shell will still need to end active operations by the end of October because of the increased chance of their being additional ice covering the drill sites later in the season.

Gray Whales—For gray whales, densities are likely to vary somewhat by season, but differences are not expected to be great enough to require estimation of separate densities for the two seasons. Gray whales are not expected to be present in large numbers in the Beaufort Sea during the fall but small numbers may be encountered during the summer. They are most likely to be present in nearshore waters. Since this species occurs infrequently in the Beaufort Sea, little to no data are available for the calculation of densities. Minimal densities have therefore been assigned for calculation purpose and to allow for chance encounters (see Table 6–3 in Shell's application and Table 3 here).

TABLE 3—EXPECTED DENSITIES OF CETACEANS (EXCLUDING BELUGA AND BOWHEAD WHALE) AND SEALS IN THE ALASKAN BEAUFORT SEA

Species	Nearshore		Ice margin	
	Average density (# /km^2)	Maximum density (# /km^2)	Average density (# /km^2)	Maximum density (# /km^2)
Odontocetes:				
Monodontidae:				
Narwhal	0.0000	0.0000	0.0000	0.0001
Phocoenidae:				
Harbor porpoise	0.0001	0.0004	0.0000	0.0000
Mysticetes:				
Gray whale	0.0001	0.0004	0.0000	0.0000
Pinnipeds:				
Bearded seal	0.0181	0.0724	0.0128	0.0512
Ribbon seal	0.0001	0.0004	0.0001	0.0004
Ringed seal	0.3547	1.4188	0.2510	1.0040
Spotted seal	0.0037	0.0149	0.0001	0.0004

(2) Pinnipeds

Extensive surveys of ringed and bearded seals have been conducted in the Beaufort Sea, but most surveys have been conducted over the landfast ice, and few seal surveys have occurred in open-water or in the pack ice. Kingsley (1986) conducted ringed seal surveys of the offshore pack ice in the central and eastern Beaufort Sea during late spring (late June). These surveys provide the most relevant information on densities of ringed seals in the ice margin zone of the Beaufort Sea. The density estimate in Kingsley (1986) was used as the average density of ringed seals that may be encountered in the ice margin (Table 6–3 in Shell's application and Table 3 here). The average ringed seal density in the nearshore zone of the Alaskan Beaufort Sea was estimated from results of ship–based surveys at times without seismic operations reported by Moulton and Lawson (2002; Table 6–3 in Shell's application and Table 3 here).

Densities of bearded seals were estimated by multiplying the ringed seal densities by 0.051 based on the proportion of bearded seals to ringed seals reported in Stirling *et al.* (1982; Table 6–3 in Shell's application and Table 3 here). Spotted seal densities in the nearshore zone were estimated by summing the ringed seal and bearded seal densities and multiplying the result by 0.015 based on the proportion of spotted seals to ringed plus bearded seals reported in Moulton and Lawson (2002; Table 6–3 in Shell's application and Table 3 here). Minimal values were assigned as densities in the ice–margin zones (Table 6–3 in Shell's application and Table 3 here).

Potential Number of Takes by Harassment

(1) Estimates of the Number of Individuals That May Be Exposed to Sounds ≥120 dB

Just because a marine mammal is exposed to drilling sounds ≥120 dB (rms), this does not mean that it will *actually* exhibit a disruption of behavioral patterns in response to the sound source. Rather, the estimates provided here are simply the best estimates of the number of animals that potentially could have a behavioral modification due to the noise. However, not all animals react to sounds at this low level, and many will not show strong reactions (and in some cases any

reaction) until sounds are much stronger. There are several variables that determine whether or not an individual animal will exhibit a response to the sound, such as the age of the animal, previous exposure to this type of anthropogenic sound, habituation, *etc.*

Numbers of marine mammals that might be present and potentially disturbed (*i.e.,* Level B harassment) are estimated below based on available data about mammal distribution and densities at different locations and times of the year as described previously. Exposure estimates are based on a single drillship (*Discoverer*) operating in Camden Bay beginning in July. Shell will not operate the *Discoverer* and associated vessels in Camden Bay during the 2010 Kaktovik and Nuiqsut (Cross Island) fall bowhead whale subsistence harvests. Shell will suspend exploration activities on August 25, prior to the beginning of the hunts, will resume activities in Camden Bay after conclusion of the subsistence harvests, and complete exploration activities on or about October 31, 2010. Actual drilling may occur on approximately 74 days while the *Discoverer* is in Camden Bay, approximately half of which would occur before and after the fall bowhead subsistence hunts.

The number of different individuals of each species potentially exposed to received levels ≥120 dB re 1 μPa within each season and habitat zone was estimated by multiplying:

- The anticipated area to be ensonified to the specified level in the time period and habitat zone to which a density applies, by
- The expected species density.

The numbers of exposures were then summed for each species across the seasons and habitat zones.

(2) Estimated Area Exposed to Sounds ≥120 dB

The total area of a 4.6 mi (7.4 km) radius circle (66.4 mi^2 [172 km^2]; representing 1.5 × the ≥120 dB radius of 3.06 mi [4.93 km] modeled by JASCO for the *Discoverer*) was used to calculate the area ensonified to ≥120 dB around the *Discoverer* operating at either of the planned drill sites (Sivulliq N and Torpedo H). This area falls within water less than 131 ft (40 m) deep at both planned locations. The area exposed to sounds by drilling occurs in waters ≤131 ft (40 m) deep, so 67 percent was multiplied by the nearshore zone densities and the remaining 33 percent by the ice-margin densities.

For analysis of potential effects on migrating bowhead whales, Shell calculated the total distance perpendicular to the migration path ensonified to ≥120 dB (4.6 mi [7.4 km] radius × 2 = 9.2 mi [14.8 km]) by the *Discoverer.* This represents 41 percent of the 22 mi (36 km) between the barrier islands and the 131 ft (40 m) bathymetry line, so it was assumed that 41 percent of the bowheads migrating within the nearshore zone (water depth 0–131 ft [0–40 m]) may be exposed to sounds ≥120 dB, if they showed no avoidance of the drilling operations.

Cetaceans—Cetacean species potentially exposed to drilling program sounds with received levels ≥120 dB would involve bowhead, gray, and beluga whales. Shell also included some maximum exposure estimates for narwhal, harbor porpoise, humpback whale, and minke whale. However, as stated previously in this document, NMFS has determined that authorizing take of these four cetacean species is not warranted because the probability of these species being present in the drilling area is remote. Average and maximum estimates of the number of individual cetaceans exposed, in descending order, are bowhead whale (1,968 and 1,977), beluga whale (1 and 4), and gray whale (0 and 5). Table 6–7 in Shell's application and Table 4 here summarize the number of marine mammal species or stocks that may experience Level B harassment.

The estimates show that one endangered cetacean species (the bowhead whale) is expected to be exposed to sounds ≥120 dB unless bowheads avoid the area around the drill sites (Tables 6–4 and 6–5 in Shell's application). Migrating bowheads are likely to do so to some extent, though many of the bowheads engaged in other activities, particularly feeding and socializing, probably will not (Richardson, 2004).

Pinnipeds—The ringed seal is the most widespread and abundant pinniped in ice-covered arctic waters, and there appears to be a great deal of year-to-year variation in abundance and distribution of these marine mammals. Ringed seals account for a large number of marine mammals expected to be encountered during the exploration drilling program, and hence exposed to sounds with received levels ≥120 dB. The average (and maximum) estimate is that 109 (436) ringed seals might be exposed to sounds with received levels ≥120 dB from the exploration drilling program.

Two additional seal species are expected to be encountered. Average and maximum estimates for bearded seal exposures to sound levels ≥120 dB were 6 and 22, respectively. For spotted seal these exposure estimates were 1 and 3, respectively. Table 6–7 in Shell's application and Table 4 here summarize the number of marine mammal species or stocks that may experience Level B harassment.

TABLE 4—SUMMARY OF THE NUMBER OF POTENTIAL EXPOSURES OF MARINE MAMMALS TO RECEIVED SOUND LEVELS IN THE WATER OF ≥120 DB AND (≥160 DB) DURING SHELL'S PLANNED EXPLORATION DRILLING PROGRAM NEAR CAMDEN BAY IN THE BEAUFORT SEA, ALASKA, JULY–OCTOBER 31, 2010

Species	Total number of exposure to sound levels >120 dB and (≥160 dB)	
	Avg.	Max.
Odontocetes:		
Monodontidae:		
Beluga	1 (0)	4 (0)
Narwhal	0 (0)	5 (5)
Phocoenidae:		
Harbor porpoise	0 (0)	5 (5)
Mysticetes:		
Bowhead whale[a]	1968 (14)	1977 (14)
Gray whale	0 (0)	5 (5)
Humpback whale	0 (0)	5 (5)

TABLE 4—SUMMARY OF THE NUMBER OF POTENTIAL EXPOSURES OF MARINE MAMMALS TO RECEIVED SOUND LEVELS IN THE WATER OF ≥120 DB AND (≥160 DB) DURING SHELL'S PLANNED EXPLORATION DRILLING PROGRAM NEAR CAMDEN BAY IN THE BEAUFORT SEA, ALASKA, JULY–OCTOBER 31, 2010—Continued

Species	Total number of exposure to sound levels >120 dB and (≥160 dB)	
	Avg.	Max.
Minke whale	0 (0)	5 (5)
Total Cetaceans	1968 (14)	1992 (29)
Pinnipeds:		
Bearded seal	6 (0)	22 (0)
Ringed seal	109 (0)	436 (0)
Ribbon seal	0 (0)	5 (5)
Spotted seal	1 (0)	5 (5)
Total Pinnipeds	115 (0)	467 (10)

Estimated Take Conclusions

As stated previously, NMFS' practice has been to apply the 120 dB re 1 μPa (rms) received level threshold for underwater continuous sound levels to determine whether take by Level B harassment occurs. However, not all animals react to sounds at this low level, and many will not show strong reactions (and in some cases any reaction) until sounds are much stronger. Southall *et al.* (2007) provide a severity scale for ranking observed behavioral responses of both free-ranging marine mammals and laboratory subjects to various types of anthropogenic sound (see Table 4 in Southall *et al.* (2007)). Tables 15, 17, and 21 in Southall *et al.* (2007) outline the numbers of low-frequency and mid-frequency cetaceans and pinnipeds in water, respectively, reported as having behavioral responses to non-pulses in 10–dB received level increments. These tables illustrate, especially for low- and mid-frequency cetaceans, that more intense observed behavioral responses did not occur until sounds were higher than 120 dB (rms). Many of the animals had no observable response at all when exposed to anthropogenic sound at levels of 120 dB (rms) or even higher.

Although the 120–dB isopleth for the drillship may seem fairly expansive (*i.e.,* 4.6 mi [7.4 km], which includes the 50 percent inflation factor), the zone of ensonification begins to shrink dramatically with each 10–dB increase in received sound level. Table 5 here depicts the radii for the 120, 130, 140, 150, and 160 dB received levels for the drillship. As stated previously, source levels are expected to be 175 dB (rms). For an animal to receive a sound at this level, it would have to be within several meters of the vessel, which is unlikely, especially give the fact that certain species are likely to avoid the area (as described earlier in this document).

TABLE 5—MODELED SOUND LEVELS AT THE 120, 130, 140, 150, AND 160 DB ISOPLETHS FOR THE DRILLSHIP—THESE DISTANCES DO NOT INCLUDE THE 50 PERCENT INFLATION FACTOR USED FOR ESTIMATING TAKE

Received levels (dB re 1 μPa rms)	Drillship (distance in m)
160	35
150	55
140	216
130	1,358
120	4,930

Table 6–7 in Shell's application and Table 4 here present the number of each species that may be exposed to sounds ≥160 dB. This number is substantially less than the number of individuals from each species that may be exposed to sounds at the 120 dB level. For example, 1,968 bowhead whales are estimated to be exposed to sounds ≥120 dB; however, only 14 bowhead whales are estimated to be exposed to sounds ≥160 dB. Additionally, using the same calculations, only 541, 86, and 22 bowhead whales are estimated to be exposed to sounds ≥130, 140, and 150 dB, respectively. Therefore, while 1,968 bowhead whales may occur within 4.6 mi (7.4 km) of the drillship, which is an area 1.5 × greater than the 120 dB radius, only a small percentage of the animals would occur in areas with received sound levels that may elicit more intense observed behavioral responses.

The ringed seal is the species with the second highest predicted encounter rate during Shell's proposed drilling program. Although there is the potential for 109 ringed seals to be exposed to sounds ≥120 dB, this number drops to zero at the 160 dB level. Additionally, using the same calculations, only 8 ringed seals are estimated to be exposed to sounds ≥130, and none are expected to be exposed to sounds at the 140–, 150—, or 160—dB levels. Moreover, fewer studies have been conducted on the reactions of pinnipeds to continuous sound sources. However, it appears that most pinnipeds are more tolerant and less responsive to sounds at lower received levels than most cetaceans, especially mysticetes.

NMFS is proposing to authorize the average take estimates provided in Table 6–7 of Shell's application and Table 4 here. The only exceptions to this are for the gray whale since the average estimate is zero and for the beluga whale to account for group size. Therefore, NMFS proposes to authorize

the take of 4 beluga whales, 1,968 bowhead whales, 5 gray whales, 6 bearded seals, 109 ringed seals, and 1 spotted seal. For beluga and gray whales, this represents 0.01 percent of the Beaufort Sea population of approximately 39,258 beluga whales (Angliss and Allen, 2009) and 0.03 percent of the Eastern North Pacific stock of approximately 17,752 gray whales. This also represents 13.8 percent of the Bering-Chukchi-Beaufort population of 14,247 individuals assuming 3.4 percent annual population growth from the 2001 estimate of 10,545 animals (Zeh and Punt, 2005). The take estimates presented for bearded, ringed, and spotted seals represent 0.1, 0.04, and 0.1 percent of the Bering-Chukchi-Beaufort populations for each species, respectively.

With the exception of the subsistence mitigation measure of shutting down during the Nuiqsut and Kaktovik fall bowhead whale hunts, these take estimates do not take into account any of the mitigation measures described previously in this document. Additionally, if the fall bowhead hunts end after September 15, and Shell still concludes activities on October 31, then fewer animals will be exposed to drilling sounds, especially bowhead whales, as more of them will have migrated past the area in which they would be exposed to sound levels of 120 dB or greater prior to Shell resuming active operations.

Lastly, even though Shell has indicated that the Camden Bay drilling program will occur for 74 days between July 10 and October 31, 2010, Shell has requested that the IHA (if issued) be valid for a full year. NMFS is proposing to grant this request in the event that Shell is unable to conduct active operations for the full 74 days. Therefore, depending on the expiration date of the IHA (if issued), Shell could potentially work early in the 2011 open-water season. The take numbers presented here (and in Shell's application) are based on 74 days of active operations. Therefore, these numbers account for this situation. In fact, these numbers may then be an overestimate, as fewer animals, especially bowhead and beluga whales, would be expected at the drill sites in early July 2011.

Negligible Impact and Small Numbers Analysis and Preliminary Determination

NMFS has defined "negligible impact" in 50 CFR 216.103 as "* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival." In making a negligible impact determination, NMFS considers a variety of factors, including but not limited to: (1) The number of anticipated mortalities; (2) the number and nature of anticipated injuries; (3) the number, nature, intensity, and duration of Level B harassment; and (4) the context in which the takes occur.

No injuries or mortalities are anticipated to occur as a result of Shell's proposed Camden Bay exploratory drilling program, and none are proposed to be authorized. Additionally, animals in the area are not expected to incur hearing impairment *(i.e.,* TTS or PTS) or non-auditory physiological effects. Takes will be limited to Level B behavioral harassment. Although it is possible that some individuals may be exposed to sounds from drilling operations more than once, during the migratory periods it is less likely that this will occur since animals will continue to move westward across the Beaufort Sea. This is especially true for bowhead whales that will be migrating past the drilling operations beginning in mid- to late September (depending on the date Shell resumes activities after the shutdown period for the fall bowhead subsistence hunts by the villages of Kaktovik and Nuiqsut).

Some studies have shown that bowhead whales will continue to feed in areas of seismic operations (*e.g.,* Richardson, 2004). Therefore, it is possible that some bowheads may continue to feed in an area of active drilling operations. It is important to note that the sounds produced by drilling operations are of a much lower intensity than those produced by seismic airguns. Should bowheads chose to feed in the ensonified area instead of avoiding the sound, individuals may be exposed to sounds at or above 120 dB (rms) for several hours to days, depending on how long the individual animal chooses to remain in the area to feed. As noted previously, many animals perform vital functions, such as feeding, resting, traveling, and socializing on a diel cycle (24-hr cycle). As discussed here, some bowhead whales may decide to remain in Camden Bay for several days to feed; however, they are not expected to be feeding for 24 hours straight each day. While feeding in an area of increased anthropogenic sound may potentially result in increased stress, it is not anticipated that the level of sound produced by the exploratory drilling operations and the amount of time that an individual whale may remain in the area to feed would result in extreme physiological stress to the animal. Additionally, if an animal is excluded from Camden Bay for feeding because it decides to avoid the ensonified area, this may result in some extra energy expenditure for the animal to find an alternate feeding ground. However, Camden Bay is one of a few feeding areas for bowhead whales in the U.S. Arctic Ocean. The disruption to feeding is not anticipated to have more than a negligible impact on the affected species or stock.

Some bowhead whales have been observed feeding in the Camden Bay area in recent years. There has also been recent evidence that some bowhead whales continued feeding in close proximity to seismic sources (*e.g.,* Richardson, 2004). The sounds produced by the drillship are of lower intensity than those produced by seismic airguns. Therefore, if animals remain in ensonified areas to feed, they would be in areas where the sound levels are not high enough to cause injury (based on the fact that source levels are not expected to reach levels known to cause even slight, mild TTS, a non-injurious threshold shift).

Beluga whales are more likely to occur in the project area after the recommencement of activities in September than in July or August. Should any belugas occur in the area of active drilling, it is not expected that they would remain in the area for a prolonged period of time, as their westward migration usually occurs further offshore (more than 37 mi [60 km]) and in deeper waters (more than 656 ft [200 m]) than that planned for the location of Shell's Camden Bay well sites. Gray whales do not frequently occur in the Camden Bay area of the Beaufort Sea, so exposures to industrial sound are not expected to last for prolonged periods (*i.e.,* several days or weeks). The exposure of cetaceans to sounds produced by exploratory drilling operations is not expected to result in more than Level B harassment and is anticipated to have no more than a negligible impact on the affected species or stock.

Some individual pinnipeds may be exposed to drilling sounds more than once during the time frame of the project. This may be especially true for ringed seals, which occur in the Beaufort Sea year-round and are the most frequently encountered pinniped species in the area. However, as stated previously in this document, pinnipeds appear to be more tolerant of anthropogenic sound, especially at lower received levels, than other marine mammals, such as mysticetes. NMFS has preliminarily determined that the exposure of pinnipeds to sounds

produced by exploratory drilling operations is not expected to result in more than Level B harassment and is anticipated to have no more than a negligible impact on the animals.

Of the six marine mammal species likely to occur in the proposed drilling area, only the bowhead whale is listed as endangered under the ESA. The species is also designated as "depleted" under the MMPA. Despite these designations, the Bering-Chukchi-Beaufort stock of bowheads has been increasing at a rate of 3.4 percent annually for nearly a decade (Allen and Angliss, 2010). Additionally, during the 2001 census, 121 calves were counted, which was the highest yet recorded. The calf count provides corroborating evidence for a healthy and increasing population (Allen and Angliss, 2010). There is no critical habitat designated in the U.S. Arctic for the bowhead whale. The bearded and ringed seals are "candidate species" under the ESA, meaning they are currently being considered for listing but are not designated as depleted under the MMPA. None of the other three species that may occur in the project area are listed as threatened or endangered under the ESA or designated as depleted under the MMPA.

Potential impacts to marine mammal habitat were discussed previously in this document (see the "Anticipated Effects on Habitat" section). Although some disturbance is possible to food sources of marine mammals, the impacts are anticipated to be minor enough as to not affect rates of recruitment or survival of marine mammals in the area. Based on the vast size of the Arctic Ocean where feeding by marine mammals occurs versus the localized area of the drilling program, any missed feeding opportunities in the direct project area would be minor based on the fact that other feeding grounds exist elsewhere.

The estimated takes proposed to be authorized represent 0.01 percent of the Beaufort Sea population of approximately 39,258 beluga whales (Angliss and Allen, 2009), 0.03 percent of the Eastern North Pacific stock of approximately 17,752 gray whales, and 13.8 percent of the Bering-Chukchi-Beaufort population of 14,247 individuals assuming 3.4 percent annual population growth from the 2001 estimate of 10,545 animals (Zeh and Punt, 2005). The take estimates presented for bearded, ringed, and spotted seals represent 0.1, 0.04, and 0.1 percent of the Bering-Chukchi-Beaufort populations for each species, respectively. These estimates represent the percentage of each species or stock that could be taken by Level B behavioral harassment if each animal is taken only once. Additionally, these numbers are likely an overestimate, as these take numbers were calculated using a 50 percent inflation factor of the 120-dB radius, which is a conservative approach recommended by some acousticians when modeling a new sound source in a new location. This is fairly conservative given the fact that the radii were based on results from a similar drillship (*i.e.,* the *Northern Explorer II*). SSV tests may reveal that the Level B harassment zone may in fact be smaller than that used to estimate take. If the SSV tests reveal that the Level B harassment zone is slightly larger than that of the *Northern Explorer II,* the 50 percent inflation factor should cover the discrepancy. Moreover, the mitigation and monitoring measures (described previously in this document) proposed for inclusion in the IHA (if issued) are expected to reduce even further any potential disturbance to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS preliminarily finds that Shell's proposed Camden Bay exploratory drilling program may result in the incidental take of small numbers of marine mammals, by Level B harassment only, and that the total taking from the exploratory drilling program will have a negligible impact on the affected species or stocks.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

Relevant Subsistence Uses

The disturbance and potential displacement of marine mammals by sounds from drilling activities are the principal concerns related to subsistence use of the area. Subsistence remains the basis for Alaska Native culture and community. Marine mammals are legally hunted in Alaskan waters by coastal Alaska Natives. In rural Alaska, subsistence activities are often central to many aspects of human existence, including patterns of family life, artistic expression, and community religious and celebratory activities. Additionally, the animals taken for subsistence provide a significant portion of the food that will last the community throughout the year. The main species that are hunted include bowhead and beluga whales, ringed, spotted, and bearded seals, walruses, and polar bears. (As mentioned previously in this document, both the walrus and the polar bear are under the USFWS' jurisdiction.) The importance of each of these species varies among the communities and is largely based on availability.

The subsistence communities in the Beaufort Sea that have the potential to be impacted by Shell's Camden Bay drilling program include Kaktovik, Nuiqsut, and Barrow. Kaktovik is a coastal community 60 mi (96.6 km) east of the project area. Nuiqsut is 118 mi (190 km) west of the project area and about 20 mi (32 km) inland from the coast along the Colville River. Cross Island, from which Nuiqsut hunters base their bowhead whaling activities, is 47 mi (75.6 km) southwest of the project area. Barrow, the community farthest from the project area, lies 298 mi (479.6 km) west of Shell's Camden Bay drill sites.

(1) Bowhead Whales

Of the three communities, Barrow is the only one that currently participates in a spring bowhead whale hunt. However, this hunt is not anticipated to be affected by Shell's activities, as the spring hunt occurs in late April to early May, and Shell's Camden Bay drilling program will not begin until July 10, at the earliest.

All three communities participate in a fall bowhead hunt. In autumn, westward-migrating bowhead whales typically reach the Kaktovik and Cross Island (Nuiqsut hunters) areas by early September, at which points the hunts begin (Kaleak, 1996; Long, 1996; Galginaitis and Koski, 2002; Galginaitis and Funk, 2004, 2005; Koski *et al.,* 2005). Around late August, the hunters from Nuiqsut establish camps on Cross Island from where they undertake the fall bowhead whale hunt. The hunting period starts normally in early September and may last as late as mid-October, depending mainly on ice and weather conditions and the success of the hunt. Most of the hunt occurs offshore in waters east, north, and northwest of Cross Island where bowheads migrate and not inside the barrier islands (Galginaitis, 2007). Hunters prefer to take bowheads close to shore to avoid a long tow, but Braund and Moorehead (1995) report that crews may (rarely) pursue whales as far as 50 mi (80 km) offshore. Whaling crews use Kaktovik as their home base, leaving the village and returning on a daily basis. The core whaling area is within 12 mi (19.3 km) of the village with a periphery ranging about 8 mi (13 km) farther, if necessary. The extreme limits of the Kaktovik whaling limit would be the

middle of Camden Bay to the west. The timing of the Kaktovik bowhead whale hunt roughly parallels the Cross Island whale hunt (Impact Assessment Inc, 1990b; SRB&A, 2009: Map 64). In recent years, the hunts at Kaktovik and Cross Island have usually ended by mid- to late September.

Westbound bowheads typically reach the Barrow area in mid-September, and are in that area until late October (Brower, 1996). However, over the years, local residents report having seen a small number of bowhead whales feeding off Barrow or in the pack ice off Barrow during the summer. Recently, autumn bowhead whaling near Barrow has normally begun in mid-September to early October, but in earlier years it began as early as August if whales were observed and ice conditions were favorable (USDI/BLM, 2005). The recent decision to delay harvesting whales until mid-to-late September has been made to prevent spoilage, which might occur if whales were harvested earlier in the season when the temperatures tend to be warmer. Whaling near Barrow can continue into October, depending on the quota and conditions.

Shell anticipates arriving on location in Camden Bay around July 10 and continuing operations until August 25. Shell has stated that it will suspend all operations on August 25 for the Nuiqsut (Cross Island) and Kaktovik subsistence bowhead whale hunts. The *Discoverer* and support vessels will leave the Camden Bay project area, will move to a location at or north of 71.25°N. latitude and at or west of 146.4°W. longitude, and will return to resume activities after the Nuiqsut (Cross Island) and Kaktovik bowhead hunts conclude. Depending on when Nuiqsut and Kaktovik declare their hunts closed, drilling operations may resume in the middle of the Barrow fall bowhead hunt.

(2) Beluga Whales

Beluga whales are not a prevailing subsistence resource in the communities of Kaktovik and Nuiqsut. Kaktovik hunters may harvest one beluga whale in conjunction with the bowhead hunt; however, it appears that most households obtain beluga through exchanges with other communities. Although Nuiqsut hunters have not hunted belugas for many years while on Cross Island for the fall hunt, this does not mean that they may not return to this practice in the future. Data presented by Braund and Kruse (2009) indicate that only one percent of Barrow's total harvest between 1962 and 1982 was of beluga whales and that it did not account for any of the harvested animals between 1987 and 1989.

There has been minimal harvest of beluga whales in Beaufort Sea villages in recent years. Additionally, if belugas are harvested, it is usually in conjunction with the fall bowhead harvest. Shell will not be operating during the Kaktovik and Nuiqsut fall bowhead harvests.

(3) Ice Seals

Ringed seals are available to subsistence users in the Beaufort Sea year-round, but they are primarily hunted in the winter or spring due to the rich availability of other mammals in the summer. Bearded seals are primarily hunted during July in the Beaufort Sea; however, in 2007, bearded seals were harvested in the months of August and September at the mouth of the Colville River Delta. An annual bearded seal harvest occurs in the vicinity of Thetis Island (which is a considerable distance from Shell's proposed Camden Bay drill sites) in July through August. Approximately 20 bearded seals are harvested annually through this hunt. Spotted seals are harvested by some of the villages in the summer months. Nuiqsut hunters typically hunt spotted seals in the nearshore waters off the Colville River delta, which is more than 100 mi (161 km) from Shell's proposed drill sites.

Although there is the potential for some of the Beaufort villages to hunt ice seals during the summer and fall months while Shell is conducting exploratory drilling operations, the primary sealing months occur outside of Shell's operating time frame. Additionally, some of the more established seal hunts that do occur in the Beaufort Sea, such as the Colville delta area hunts, are located a significant distance (in some instances 100 mi [161 km] or more) from the proposed project area.

Potential Impacts to Subsistence Uses

NMFS has defined "unmitigable adverse impact" in 50 CFR 216.103 as:

> * * * an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

Noise and general activity during Shell's proposed drilling program have the potential to impact marine mammals hunted by Native Alaskans. In the case of cetaceans, the most common reaction to anthropogenic sounds (as noted previously in this document) is avoidance of the ensonified area. In the case of bowhead whales, this often means that the animals divert from their normal migratory path by several kilometers. Helicopter activity also has the potential to disturb cetaceans and pinnipeds by causing them to vacate the area. Additionally, general vessel presence in the vicinity of traditional hunting areas could negatively impact a hunt.

In the case of subsistence hunts for bowhead whales in the Beaufort Sea, there could be an adverse impact on the hunt if the whales were deflected seaward (further from shore) in traditional hunting areas. The impact would be that whaling crews would have to travel greater distances to intercept westward migrating whales, thereby creating a safety hazard for whaling crews and/or limiting chances of successfully striking and landing bowheads.

Plan of Cooperation (POC)

Regulations at 50 CFR 216.104(a)(12) require IHA applicants for activities that take place in Arctic waters to provide a POC or information that identifies what measures have been taken and/or will be taken to minimize adverse effects on the availability of marine mammals for subsistence purposes. Shell has developed a Draft POC for its 2010 Camden Bay, Beaufort Sea, Alaska, exploration drilling program to minimize any adverse impacts on the availability of marine mammals for subsistence uses. A copy of the Draft POC was distributed to the communities, subsistence user groups, NMFS, and other Federal and State agencies in May 2009. An updated Communications Plan was then submitted to NMFS as an attachment to the POC in July 2009. Shell conducted POC meetings throughout 2009 regarding its planned 2010 activities in both the Beaufort and Chukchi Seas. During these meetings, Shell focused on lessons learned from prior years' activities and presented mitigation measures for avoiding potential conflicts, which are outlined in the 2010 POC and this document. For this Camden Bay drilling program, Shell's POC with Chukchi Sea villages primarily addresses the issue of transit of vessels, whereas the POC with Beaufort Sea villages addresses vessel transit, drilling, and associated activities. Communities that were consulted regarding Shell's 2010 Arctic

Ocean operations include: Barrow, Kaktovik, Wainwright, Kotzebue, Kivalina, Point Lay, and Point Hope. Attempts were made to meet individually with whaling captains and to hold a community meeting in Nuiqsut; however, after receipt of a request by the Mayor, the scheduled meeting was cancelled. Shell subsequently sent correspondence to all post office box holders in Nuiqsut on February 26, 2009, indicating its willingness to visit and have dialogue on the proposed plans.

Beginning in early January 2009, Shell held one-on-one meetings with representatives from the North Slope Borough (NSB) and Northwest Arctic Borough (NWAB), subsistence-user group leadership, and Village Whaling Captain Association representatives. Shell's primary purpose in holding individual meetings was to inform and prepare key leaders, prior to the public meetings, so that they would be prepared to give appropriate feedback on planned activities.

Shell presented the proposed project to the NWAB Assembly on January 27, 2009, to the NSB Assembly on February 2, 2009, and to the NSB and NWAB Planning Commissions in a joint meeting on March 25, 2009. Meetings were also scheduled with representatives from the Alaska Eskimo Whaling Commission (AEWC), and presentations on proposed activities were given to the Inupiat Community of the Arctic Slope, and the Native Village of Barrow. A full list of POC meetings conducted by Shell between January and April 2009 can be found in Table 4.2–1 of Shell's POC. Shell has successfully completed additional POC meetings with several communities since submitting the Draft POC, including:

- June 1, 2009: NSB Assembly meeting;
- June 2, 2009: Point Lay meeting with village leadership;
- June 3, 2009: Kaktovik meeting with village leadership;
- June 17, 2009: Point Hope meeting with village leadership;
- August 5, 2009: NWAB Assembly meeting; and
- August 27, 2009: NSB Planning Commission meeting.

On December 8, 2009, Shell held consultation meetings with representatives from the various marine mammal commissions. Prior to drilling in 2010, Shell will also hold additional consultation meetings with the affected communities and subsistence user groups, NSB, and NWAB to discuss the mitigation measures included in the POC.

The following mitigation measures, plans and programs, are integral to the POC and were developed during consultation with potentially affected subsistence groups and communities. These measures, plans, and programs will be implemented by Shell during its 2010 exploration drilling operations in both the Beaufort and Chukchi Seas to monitor and mitigate potential impacts to subsistence users and resources. The mitigation measures Shell has adopted and will implement during its 2010 Camden Bay exploration drilling operations are listed and discussed below. This most recent version of Shell's planned mitigation measures was presented to community leaders and subsistence user groups starting in January of 2009 and has evolved since in response to information learned during the consultation process.

To minimize any cultural or resource impacts to subsistence whaling activities from its exploration operations, Shell will suspend drilling activities on August 25, 2010, prior to the start of the Kaktovik and Cross Island bowhead whale hunting season. The drillship and associated vessels will remain outside of the Camden Bay area during the hunt. Shell will resume drilling operations after the conclusion of the hunt and, depending on ice and weather conditions, continue its exploration activities through October 31, 2010. In addition to the adoption of this project timing restriction, Shell will implement the following additional measures to ensure coordination of its activities with local subsistence users to minimize further the risk of impacting marine mammals and interfering with the subsistence hunts for marine mammals:

(1) The drillship and support vessels will transit through the Chukchi Sea along a route that lies offshore of the polynya zone. In the event the transit outside of the polynya zone results in Shell having to break ice (as opposed to managing ice by pushing it out of the way), the drillship and support vessels will enter into the polynya zone far enough so that ice breaking is not necessary. If it is necessary to move into the polynya zone, Shell will notify the local communities of the change in the transit route through the Communication Centers (Com Centers);

(2) Shell has developed a Communication Plan and will implement the plan before initiating exploration drilling operations to coordinate activities with local subsistence users as well as Village Whaling Associations in order to minimize the risk of interfering with subsistence hunting activities and keep current as to the timing and status of the bowhead whale migration, as well as the timing and status of other subsistence hunts. The Communication Plan includes procedures for coordination with Com and Call Centers to be located in coastal villages along the Chukchi and Beaufort Seas during Shell's proposed activities in 2010;

(3) Shell will employ local Subsistence Advisors from the Beaufort and Chukchi Sea villages to provide consultation and guidance regarding the whale migration and subsistence hunt. There will be a total of nine subsistence advisor-liaison positions (one per village), to work approximately 8-hours per day and 40-hour weeks through Shell's 2010 exploration project. The subsistence advisor will use local knowledge (Traditional Knowledge) to gather data on subsistence lifestyle within the community and advise as to ways to minimize and mitigate potential impacts to subsistence resources during the drilling season. Responsibilities include reporting any subsistence concerns or conflicts; coordinating with subsistence users; reporting subsistence-related comments, concerns, and information; and advising how to avoid subsistence conflicts. A subsistence advisor handbook will be developed prior to the operational season to specify position work tasks in more detail;

(4) Shell will recycle drilling muds (*e.g.,* use those muds on multiple wells), to the extent practicable based on operational considerations (*e.g.,* whether mud properties have deteriorated to the point where they cannot be used further), to reduce discharges from its operations. At the end of the season excess water base fluid will be pre-diluted to a 30:1 ratio with seawater and then discharged;

(5) Shell will implement flight restrictions prohibiting aircraft from flying within 1,000 ft (305 m) of marine mammals or below 1,500 ft (457 m) altitude (except during takeoffs and landings or in emergency situations) while over land or sea; and

(6) No routine vessel traffic will traverse the subsistence area. Vessels within 900 ft (274 m) of marine mammals will reduce speed, avoid separating members from a group, and avoid multiple changes in direction.

For several years, a Conflict Avoidance Agreement (CAA) has been negotiated between the AEWC, affected whaling captains' associations, and the oil and gas industry to avoid conflicts between industry activity and bowhead whale subsistence hunts. While the signing of a CAA is not a requirement to obtain an IHA, often times, the CAA

contains measures that help NMFS make its no unmitigable adverse impact determination for bowhead whales. Shell is currently reviewing the draft 2010 CAA and is expected to make a decision on whether or not it will sign the 2010 CAA prior to commencing operations this year.

Unmitigable Adverse Impact Analysis and Preliminary Determination

NMFS has preliminarily determined that Shell's proposed Camden Bay exploration drilling program will not have an unmitigable adverse impact on the availability of species or stocks for taking for subsistence uses. This preliminary determination is supported by information contained in this document and Shell's POC. Shell has adopted a spatial and temporal strategy for its Camden Bay operations that should minimize impacts to subsistence hunters. First, Shell's activities will not commence until after the spring hunts have occurred. Additionally, Shell will traverse the Chukchi Sea far offshore, so as to not interfere with July hunts in the Chukchi Sea and will communicate with the Com Centers to notify local communities of any changes in the transit route. Once Shell is on location in Camden Bay, Beaufort Sea, whaling will not commence until late August/early September. Shell has agreed to cease operations on August 25 to allow the villages of Kaktovik and Nuiqsut to prepare for the fall bowhead hunts, will move the drillship and all support vessels out of the hunting area so that there are no physical barriers between the marine mammals and the hunters, and will not recommence activities until the close of both villages' hunts.

Kaktovik is located 60 mi (96.6 km) east of the project area. Therefore, westward migrating whales would reach Kaktovik before reaching the area of Shell's activities or any of the ensonified zones. Although Cross Island and Barrow are west of Shell's drill sites, sound generating activities from Shell's drilling program will have ceased prior to the whales passing through the area. Additionally, Barrow lies 298 mi (479.6 km) west of Shell's Camden Bay drill sites, so whalers in that area would not be displaced by any of Shell's activities.

Adverse impacts are not anticipated on sealing activities since the majority of hunts for seals occur in the winter and spring, when Shell will not be operating. Sealing activities in the Colville River delta area occur more than 100 mi (161 km) from Shell's Camden Bay drill sites.

Shell will also support the village Com Centers in the Arctic communities and employ local Subsistence Advisors from the Beaufort and Chukchi Sea villages to provide consultation and guidance regarding the whale migration and subsistence hunt. The Subsistence Advisors will provide advice to Shell on ways to minimize and mitigate potential impacts to subsistence resources during the drilling season.

Based on the measures described in Shell's Draft POC, the proposed mitigation and monitoring measures (described earlier in this document), and the project design itself, NMFS has determined preliminarily that there will not be an unmitigable adverse impact on subsistence uses from Shell's Camden Bay exploration drilling activities.

Endangered Species Act (ESA)

There is one marine mammal species listed as endangered under the ESA with confirmed or possible occurrence in the proposed project area: The bowhead whale. NMFS' Permits, Conservation and Education Division has initiated consultation with NMFS' Endangered Species Division under section 7 of the ESA on the issuance of an IHA to Shell under section 101(a)(5)(D) of the MMPA for this activity. Consultation will be concluded prior to a determination on the issuance of an IHA.

National Environmental Policy Act (NEPA)

NMFS is currently preparing an Environmental Assessment, pursuant to NEPA, to determine whether or not this proposed activity may have a significant effect on the human environment. This analysis will be completed prior to the issuance or denial of the IHA.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to authorize the take of marine mammals incidental to Shell's 2010 Camden Bay, Beaufort Sea, Alaska, exploration drilling program, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: April 12, 2010.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

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