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Title 3—

The President

Proclamation 7682 of May 23, 2003

National Missing Children's Day, 2003

By the President of the United States of America

A Proclamation

On National Missing Children's Day, we join with families, law enforcement officials, and child advocates to highlight our commitment to stopping the abduction and exploitation of children. During this year's observance, we celebrate the progress we have made in safeguarding children, and we renew our dedication to protecting our most vulnerable citizens and our most valuable resources.

The Department of Justice estimates that more than 50,000 children will be victims of nonfamily abductions each year. While the rate of recovery in such kidnappings is approximately 99 percent, the trauma of abduction affects far too many. No young person in America should ever know the terror of abduction, and no family should ever have to experience the nightmare of having a loved one suddenly taken.

The safety and well-being of our children is a shared responsibility for all Americans and for Federal, State, and local authorities. My Administration is making the prevention and investigation of child abductions a top priority. We are working to use available resources to educate our citizens about how to prevent child abductions. We are also creating new lines of communication between authorities and the public to help find and safely return missing children to their families. We will continue to vigorously prosecute and severely punish those who would harm our children.

To further these efforts, in August 2002, my Administration released a new guidebook, ''Personal Safety for Children: A Guide for Parents'' to teach parents steps to improve their children's safety. Since then, copies have been distributed to public and private schools and public libraries throughout the country, in both English and Spanish. In October 2002, I convened the first White House Conference on Missing, Exploited, and Runaway Children to promote public awareness of the issues and to generate recommendations and best practices from experts. And in December 2002, I signed legislation creating the Dot Kids domain, a child-friendly zone on the Internet. The sites on this domain are monitored for content and safety, offering parents peace of mind knowing that their children can learn in a safe and healthy environment.

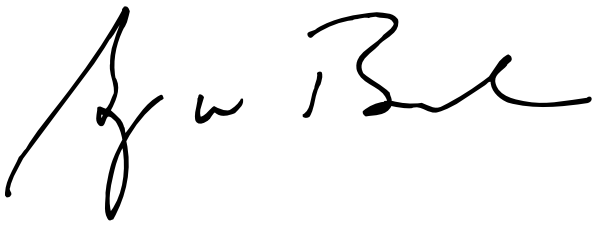
Last month I signed the PROTECT Act, an important law that provides valuable new ways to deter, investigate, prosecute, and punish crimes against America's children. The PROTECT Act also builds on my Administration's ongoing efforts to expand and improve the AMBER Alert program, which has become an increasingly important tool to help rescue kidnapped children by quickly getting key information about the missing child and the suspect to the public. This law formally establishes the Federal Government's role in the AMBER Alert system and equips the Department of Justice to help State and local officials develop, enhance, and coordinate AMBER plans across America.

Our Nation has come to know the names and faces of far too many children because they have been the victims of acts of cruelty and violence. These crimes break our hearts and stir our anger. Our Nation shares the joy of

the parents who are reunited with their children, and prays with those who are still hoping and waiting. We grieve with every family that has suffered the loss of or injury to a child. We will continue the fight against the threats that our children face.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim May 25, 2003, as National Missing Children's Day. I call upon Americans to join me in commemorating this observance by celebrating those children who have been returned to their loved ones, remembering those young people who are missing, and continuing to work together on every front to protect our children from those who would seek to harm them.

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



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Rules and Regulations

Federal Register
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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93 and 94

[Docket No. 03–058–1]

Change in Disease Status of Canada Because of BSE

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations by adding Canada to the list of regions where bovine spongiform encephalopathy exists because the disease has been detected in an animal in that region. This action prohibits or restricts the importation of ruminants that have been in Canada and meat, meat products, and certain other products and byproducts of ruminants that have been in Canada. This action is necessary to help prevent the introduction of bovine spongiform encephalopathy into the United States.

DATES: This rule is effective retroactively to May 20, 2003. We will consider all comments that we receive on or before July 28, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–058–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–058–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 03–058–1'' on the subject line.

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

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

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Director, Sanitary Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a neurological disease of cattle and is not known to exist in the United States. It appears that BSE is primarily spread through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Therefore, BSE could become established in the United States if materials carrying the BSE agent, such as certain meat, animal products, and animal byproducts from ruminants, are imported into the United States and are fed to ruminants in the United States. BSE could also become established in the United States if ruminants with BSE are imported into the United States.

Sections 94.18, 95.4, and 96.2 of the regulations prohibit or restrict the importation of certain meat and other animal products and byproducts from ruminants that have been in regions in which BSE exists or in which there is an undue risk of introducing BSE into the United States. Paragraph (a)(1) of § 94.18 lists the regions in which BSE exists. Paragraph (a)(2) lists the regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be acceptable for import into the United States and/or because the regions have inadequate surveillance. Paragraph (b) of § 94.18 prohibits the importation of fresh, frozen, and chilled meat, meat products, and most other edible products of ruminants that have been in any region listed in paragraphs (a)(1) or (a)(2). Paragraph (c) of § 94.18 restricts the importation of gelatin derived from ruminants that have been in any of these regions. Section 95.4 prohibits or restricts the importation of certain byproducts from ruminants that have been in any of those regions, and § 96.2 prohibits the importation of casings, except stomach casings, from ruminants that have been in any of these regions. Additionally, the regulations in part 93 pertaining to the importation of live animals provide that the Animal and Plant Health Inspection Service (APHIS) may deny an application for a permit for the importation of ruminants from regions where a communicable disease such as BSE exists and from regions that present risks of introducing communicable diseases into the United States (*see* § 93.404(a)(3)).

On May 20, 2003, the Canadian Food Inspection Agency reported a case of BSE in a beef cow in northern Alberta. Therefore, in order to prevent the introduction of BSE into the United States, we are amending § 94.18(a)(1) by adding Canada to the list of regions where BSE is known to exist. This action prohibits or restricts the importation of ruminants that have been in Canada and the importation of meat, meat products, and certain other products and byproducts of ruminants that have been in Canada. We are making this amendment effective retroactively to May 20, 2003, which is the date that Canada reported the BSE case.

As noted previously, the regulations in § 93.404(a)(3) provide the basis for APHIS to deny an application for a permit for the importation of ruminants from regions listed in § 94.18(a)(1) or (a)(2). Because, with certain exceptions, ruminants may not be imported into the

United States unless their importation is authorized by a permit, the provisions of § 93.404(a)(3) have been sufficient to prevent the entry of live ruminants from regions affected with BSE. However, the regulations in part 93 provide exemptions from the permit requirement for ruminants from several regions, including Canada, under certain circumstances. Given that the denial of a permit application may not serve in all cases to provide a regulatory basis for preventing the importation of ruminants from regions affected with BSE, we have amended the regulations in § 93.401, ''General prohibitions; exceptions,'' to include an explicit prohibition on the importation of ruminants that have been in any region listed in § 94.18(a)(1) or (a)(2).

Emergency Action

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

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

Executive Order 12866 and Regulatory Flexibility Act

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

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

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has retroactive effective to May 20, 2003; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

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

List of Subjects

9 CFR Part 93

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

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 93 and 94 as follows:

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

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

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

■ 2. In § 93.401, paragraph (a) is revised to read as follows:

§ 93.401 General prohibitions; exceptions.

(a) No ruminant or product subject to the provisions of this part shall be brought into the United States except in accordance with the regulations in this part and part 94 of this subchapter;[3] nor shall any such ruminant or product be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations. Notwithstanding any other provision of this subpart, the importation of any ruminant that has been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter is prohibited. *Provided, however,* the Administrator may upon request in specific cases permit ruminants or products to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock or poultry of the United States.

* * * * *

PART 94—RINDERPEST, FOOT–AND–MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 3. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

§ 94.18 [Amended]

■ 4. In § 94.18, paragraph (a)(1) is amended by adding, in alphabetical order, the word ''Canada,''.

Done in Washington, DC, this 23rd day of May, 2003 .

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–13440 Filed 5–28–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 02–109–3]

Importation of Beef From Uruguay

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from Uruguay. Based on the evidence presented in a recent risk assessment, we believe that fresh (chilled or frozen) beef can be safely imported from Uruguay provided certain conditions are met. This action will provide for the importation of beef from Uruguay into the United States while continuing to protect the United States against the introduction of foot-and-mouth disease.

EFFECTIVE DATE: May 29, 2003.

FOR FURTHER INFORMATION CONTACT: Dr. Hatim Gubara, Senior Staff Veterinarian, Regionalization Evaluation Services Staff, VS, APHIS, 4700 River Road Unit

[3] Importations of certain animals from various regions are absolutely prohibited under part 94 because of specified diseases.

38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including rinderpest, foot-and-mouth disease (FMD), African swine fever, hog cholera, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine. Section 94.1 of the regulations lists regions of the world that are considered free of rinderpest or free of both rinderpest and FMD. The Animal and Plant Health Inspection Service (APHIS) considers rinderpest or FMD to exist in all regions of the world not listed.

On February 10, 2003, we published in the **Federal Register** a proposed rule (68 FR 6673–6677, Docket No. 02–109–1) to amend the regulations by allowing the importation of fresh (chilled or frozen) beef from Uruguay provided certain conditions were met. In that proposed rule, we notified the public of the availability of a risk assessment entitled, ''Risk Assessment—Importation of Fresh (chilled or frozen) Beef from Uruguay'' (November 2002).

We solicited comments concerning the proposed rule and the risk assessment for 60 days ending April 11, 2003. On April 14, 2003, we published in the **Federal Register** a notice (68 FR 17886, Docket No. 02–109–2) in which we reopened and extended the comment period for a period of 2 weeks ending April 25, 2003. We received a total of 28 comments by that date. The comments were submitted by domestic cattle producers, domestic cattle and livestock associations, a food company, a trade association, a State department of agriculture, a State public lands council, State veterinarians, foreign livestock associations, a representative of a foreign government, and other members of the public. Five commenters were supportive of the proposed rule, and three additional commenters generally supported the proposed rule provided APHIS continues to evaluate the validity and efficacy of the mitigation measures. The other commenters expressed concern about the effects of the proposed rule and about some of the specific provisions of the proposal. These comments are discussed by subject below.

Trade Issues

Several commenters expressed concern that there would be negative economic effects on the domestic cattle industry if fresh beef is allowed to be imported from Uruguay. Under its statutory authority, APHIS may prohibit or restrict the importation or entry of any animal or article in order to prevent the introduction or dissemination of a pest or disease of livestock. APHIS does not, however, have authority to restrict trade based on its potential economic effects. It should be noted, however, that past importations of fresh beef from Uruguay have comprised 0.2 percent or less of the total U.S. beef supply.

Equivalency and Verification Issues

Several commenters expressed concerns that Uruguay's health environment, level of management of disease control, and epidemiology are not equivalent to those of the United States. Based on our evaluation of information obtained from Uruguay, from APHIS site visits to that country, and from periodic visits conducted by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), we have concluded that Uruguay's health standards, demonstrated ability to implement effective disease control methods in the event of an outbreak, and familiarity with modern epidemiology are effective.

One commenter stated that APHIS ''needs to verify that the Uruguay FMD surveillance program is valid and that Uruguay is indeed free of the virus'' and that ''if APHIS confirms that FMD has been eliminated it must verify that the mitigating measures of de-boning, no blood clots, lymphatic tissue, and a pH of 5.8 or less is achieved in Uruguay.'' The commenter also stated that ''[i]f these steps are verified, a wealth of scientific data indicates beef from Uruguay will not pose an FMD threat to the United States.'' Three commenters asked if APHIS had evaluated Uruguay's FMD surveillance program, processing system, and mitigation measures. One commenter stated that ''APHIS must also verify that these mitigating measures are being conducted in an adequate manner in Uruguay.* * *'' Three commenters suggested that evaluation teams include State laboratory officials, representatives of APHIS, the U.S. Food and Drug Administration (FDA), State animal health officials, and industry representatives. One commenter stated that more stringent inspections by non-Uruguayan officials are needed. Some of these commenters asked whether we would develop a verification plan.

We evaluate each request for initiation or resumption of trade in animals or animal products with foreign countries individually. The complete review process involves a thorough evaluation of the relevant infrastructure of the individual country by technical experts with experience in country disease evaluation and risk assessment. The risk assessment process, which is detailed below, is implemented specifically to evaluate and verify the efficacy of the surveillance programs, border controls, processing systems, and other disease control measures of the country in question.

The information is evaluated by personnel from APHIS's National Center for Import and Export (NCIE); Centers for Epidemiology and Animal Health (CEAH), which is an Office International des Epizooties (OIE) collaborating center for risk assessment and surveillance;[1] other Veterinary Services (VS) personnel, as appropriate; personnel from the National Veterinary Services Laboratories (NVSL); and personnel from APHIS's International Services who have first-hand knowledge of the animal health conditions in the region under evaluation. APHIS reviews the information provided by foreign government officials for completeness and acceptability with regard to all of the factors for evaluation listed in 9 CFR 92.2, ''Application for recognition of the animal health status of a region.'' Topics covered in this review include, but are not limited to, border controls, surveillance, slaughter/processing plant controls, and security of sample integrity. In addition, the evaluation addresses effectiveness of veterinary infrastructure, disease status of the region, status of adjacent regions, disease control programs, vaccination status, separation of the region from adjacent higher risk regions, animal movement controls, livestock demographics and marketing practices, laboratory capabilities, and emergency response capabilities. APHIS requests additional information, if necessary, and seeks relevant information from other sources such as published literature.

Once the information provided by foreign officials is considered sufficient to conclude that the risks are low enough that the evaluation may proceed, a site visit to the region is

[1] In 1998, the OIE designated CEAH as a Collaborating Center for Risk Analysis and Animal Disease Surveillance Systems. The OIE is the international animal health standard-setting organization recognized by the World Trade Organization. The role of the collaborating center is to provide member countries of the OIE with scientific and technical assistance and expert advice on topics linked to animal health risk analysis and disease surveillance and control.

scheduled. In addition to representation by VS personnel, the site review team also includes field personnel from APHIS's International Services, a State veterinarian, and, if a quantitative model is used to assess risk, individuals with expertise in quantitative risk analysis techniques.

We believe that the disease evaluation expertise of personnel from NCIE and CEAH, with input as appropriate from other APHIS units for additional expertise in quantitative risk analysis techniques and in-country conditions, and the foreign animal disease (FAD) laboratory expertise of NVSL are adequate for these evaluations. We do not include FDA personnel, as FAD evaluations are not within the FDA's authority or expertise. We do not include State laboratory personnel since FAD laboratory expertise is provided by NVSL.

Industry representatives have not historically participated in APHIS evaluations. APHIS believes that it is not appropriate to include industry commodity groups on country evaluation teams for several reasons, but primarily because industry participation might make it appear that the review is not impartial. Inclusion of industry representatives might generate the appearance of, and potential for, conflicts of interest between the U.S. and foreign industry interests. In addition, APHIS questions whether information would be provided freely by foreign governments and commercial interests if U.S. industry representatives were present. In this regard, the site visit teams typically include visits to commercial facilities that might be unwilling to openly exchange commercial or proprietary information, which is critical to the verification and evaluation process. Also from a practical standpoint, industry representation would be necessarily limited to a very few individuals representing a very limited spectrum of the industry, thereby possibly providing a competitive advantage for participants. Further, inclusion of industry representation on a team that will provide recommendations to the agency could raise concerns under the Federal Advisory Committee Act unless the team was formally chartered as a Federal advisory committee. This would not be feasible for site visit teams.

The information obtained from these reviews is used to conduct an assessment of the risk of importation of the requested commodity. The risk assessments APHIS prepares are made available for public review prior to any final rulemaking. All comments from the public are considered in the final decisionmaking process.

Uruguay's surveillance program, border controls, and processing and slaughter controls, as well as its implementation of various mitigation measures, have all been evaluated during our site visits in preparation for the risk assessment. Evidence of the effectiveness of the measures being taken is presented in the risk assessment. Periodic visits to the slaughtering establishments are also conducted by FSIS. Although we do not conduct scheduled, annual visits to the processing plants, we note that we have an APHIS representative who is permanently located in Uruguay, and that all processing plants approved for export must allow periodic on-site evaluation and subsequent inspection of their facilities, records, and operations by an APHIS representative at our request. We will continue to monitor the situation in Uruguay and will conduct reinspections if we feel they are necessary.

We do not consider it necessary to establish a specific verification plan for Uruguay. In fact, on March 6, 2003, we published in the **Federal Register** (68 FR 10667, Docket No. 01–036–1) a proposed rule that, if made final, will reinforce our current authority to reevaluate regions when there is a reason for concern.

Several commenters asked whether we will provide for reinspection of fresh beef from Uruguay at the U.S. port of first arrival to verify that all mitigation measures, including measurement of pH levels, have been effectively and adequately carried out. Based on the evidence in the risk assessment and the site visit report regarding Uruguay's effective implementation of the required mitigation measures, reinspection would be unlikely to provide additional risk mitigation. Reinspection at the port of first arrival would be a valid safeguard only if it could provide verification of the pH level of the beef at the time of maturation. Variations in pH levels during cold storage, freezing, and transport, however, would make it very difficult to obtain data that can be correlated with pH levels at the time of maturation. Therefore, the type of reinspection upon arrival suggested by the commenters would offer no additional protection. Inspectors at the port of first arrival will, however, monitor all shipments that come into the United States and verify that the beef is accompanied by the foreign meat inspection certificates required under this rule to ensure that all requirements have been met.

One commenter stated that we should enforce documentation measures to protect against the possibility of transshipment (*i.e.,* beef from Uruguay being shipped through another FMD-affected country while en route to the United States). The regulations in § 94.1(d) provide conditions that must be met in order for fresh (chilled or frozen) meat that enters a port or otherwise transits a region where rinderpest or FMD exists to be eligible for importation into the United States. Those conditions include certification requirements and safeguarding measures, including the use of official seals, to prevent the meat from coming into contact with any other cargo or being handled during transit. However, the provisions of § 94.1(d) apply specifically to the transshipment of fresh (chilled or frozen) meat of ruminants or swine raised and slaughtered in a region free of FMD and rinderpest. Therefore, in response to this comment, we are amending § 94.1(d) in this final rule to provide that the conditions in that paragraph also apply to fresh (chilled or frozen) beef from Uruguay. We are also amending paragraph (b) of § 94.1, which refers to the provisions of paragraph (d), to reflect this change.

Technical Questions

Two commenters expressed concern about the risk posed by formerly exposed cattle who can carry the FMD virus in the oropharynx, where it can persist for between 30 and 36 months and be preserved by refrigeration or freezing. According to Thomson (1994) [2], recovered cattle or vaccinated cattle that had been exposed to diseased animals, the FMD virus was found only in the pharyngeal area of carriers, and in only minute quantities. This virus usually is bound to antibodies and virus inhibitors. In general, carriers have high levels of circulating antibodies. Carrier animals do not have the virus in the blood (viremia), bone marrow, lymph nodes, or muscle tissue. In addition, the head, in which the oropharynx is located, is one of the bovine parts that is prohibited importation.

We proposed that beef imported from Uruguay must come from bovine carcasses that were allowed to maturate for a minimum of 36 hours after slaughter and that reached a pH of 5.8 or less in the loin muscle at the end of the maturation period. We also proposed that any carcass in which the

[2] Thomson, G., ''Foot-and-Mouth Disease,'' Infectious Diseases of Livestock (ed. Coetzer, Thomson and Tustin). Chapter 2, pp 825–852, Oxford University Press. Capt Town, South Africa, 1994.

pH did not reach 5.8 after 36 hours could maturate an additional 24 hours and be retested. If the carcass had not reached a pH of 5.8 or less after 60 hours, the meat from the carcass could not be exported to the United States. Several commenters stated that, based on OIE standards, standards of specific international markets, and cited studies, the minimum maturation time for beef from countries where vaccination is practiced should be 24 hours rather than the 36 hours that we proposed, with an additional 12 hours allowed for beef that had not reached 5.8 or less after 24 hours. The commenters stated that a minimum maturation time of 36 hours is cost prohibitive and logistically difficult to maintain. One of the commenters stated that the pH level in beef tends to rise when maturation time exceeds 24 hours.

We are making no changes based on these comments. The scientific literature available to us does not support the statement that the pH level in beef tends to rise when maturation time exceeds 24 hours. Available literature showed that there is a gradual trend towards lower pH with time and that the pH averages 5.6 to 5.8 after 48 hours of aging, although the pH does tend to rise slightly after 72 to 96 hours of maturation.[3] Other research indicated that, although the FMD virus survived for 24 hours in beef stored at 4 °C, the virus was inactivated by the third day after the pH had declined.[4]

The data used in our risk assessment for the proposed rule change comes from our site visits and from data provided by Uruguay. Because all plants in Uruguay currently operate according to the European Union's (EU) requirement of a minimum of 24 hours of maturation and a pH level of less than 6.0, the only data available to us were for the number of carcasses in Uruguay that failed to meet that level. That rejection rate was used in assessing the proportion of viremic carcasses that could pass undetected through the processing system. However, because the current rejection rate is based on a pH threshold of less than 6.0, APHIS' requirement of pH 5.8 could increase the rejection rate by an unknown amount. Since we are requiring a minimum maturation time of 36 hours, and the literature indicates a gradual trend towards lower pH over time, we considered it unlikely that the rejection rate will increase significantly. Using that information, we concluded that fresh beef could be imported from Uruguay in accordance with the conditions described in the proposed rule without an unacceptable risk of FMD being present in the beef. Because no data are available to us regarding the rejection rate at pH 5.8 or less after a minimum of 24 hours of maturation, we are retaining the requirement that fresh beef from Uruguay undergo maturation for a minimum of 36 hours and reach a pH of 5.8 or less.

One commenter stated that pH measurements should be taken at the middle of both *longissimus dorsi* muscles. Although we did not specify this requirement in the proposed rule because it is common practice, for clarity's sake we are including it in the final rule.

Because of the importance of proper pH measurements, one commenter asked (1) how we will verify that Uruguayan processing plants use the best available pH testing technology, (2) if we will initiate an approved pH meter standard, (3) if we will require the processing plants to have standard operating procedures for the use of pH meters on file, and (4) if we will require them to record pH meter serial numbers and document their meter standardization. Another commenter requested that a certified U.S. veterinary official oversee all pH testing and verify that conditions at slaughter facilities are equivalent to U.S. standards. One commenter requested that APHIS require the presence of a full-time APHIS or FSIS inspector to ensure that all processing is done in compliance with U.S. standards.

The pH control in Uruguay is regulated under the Government of Uruguay's Procedure 2001/2, ''Generic procedure for maturation and pH control in bovine and ovine meat and offal'' and Circular 2002/4, ''Procedure for official verification of the calibration of pH measuring devices for meat.'' The former procedure specifies time and temperature for the maturation process and requires that all meat processed for export be pH-tested. The latter procedure requires calibration of pH measuring devices at the beginning of each workday and after every 200 measurements. Other Uruguayan requirements include official control of the preparation and storage of buffer solutions.

As noted in our site visit report, we evaluated pH control procedures at the San Jacinto plant, which exports to the EU and to other countries, during the July 2002 site visit to Uruguay. We verified that the instrument used to measure pH is calibrated according to the manufacturer's specifications. There is a laboratory in the plant where pH calibration takes place on a daily basis. Calibration and rejection records were examined and verified. All records were found to be adequate. In addition, we verified that pH testing is done by plant personnel under strict supervision by official inspectors. We concluded that adequate pH measuring technologies are available at export plants and that calibration of devices and control of pH inspection is carried out under the control of official authorities. Based on this evidence, we do not believe it is necessary for this rule to require an additional approved pH meter standard or to specifically require every plant keep its standard operating procedures for the use of pH meters on file, to record pH meter serial numbers, and to document their meter standardization, since these measures are already required by the Uruguayan government and all of the necessary documentation and procedures are already on file in each plant. Nor do we consider continuous APHIS supervision of the process necessary. However, this rule provides that APHIS reserves the right to conduct reinspections at any time that we feel it is necessary.

One commenter noted that, according to two studies,[5] pH can change slightly during cold storage. As a result, although beef may have achieved a pH of 5.8 or less in Uruguay, upon arrival in the United States the pH level may have increased slightly. The commenter requested that APHIS develop a project to collect pH data from specific lots of beef destined for export to the United States and then to verify the pH upon departure and arrival in order to establish a baseline of pH changes during transport. This baseline could then be used to verify that the beef had reached a pH of 5.8 during the maturation process in Uruguay.

The variations in pH level fluctuations would make it difficult, if not impossible, to correlate the pH levels of beef arriving in the United States with the pH levels that had been achieved at maturation in Uruguay. We do not believe that a project of this type would offer meaningful data or provide additional protection. Additionally, for the reason discussed previously, we consider the pH readings reported by Uruguayan officials to be sufficient.

One commenter noted that although the risk assessment states that

[3] Cottral *et al.,* ''The Survival of Foot-and-Mouth Disease Virus in Cured and Uncured Meat,'' American Journal of Veterinary Research, 1960, pp 288–297.

[4] Henderson, W. and Brooksby, J., ''The Survival of Food-and-Mouth Disease in Meat and Offal,'' Journal Hyg. Camb., 1948, 46(4):394–402.

[5] Sair, L. and Cook, W.H., Canadian Journal of Research, 16 (section D, No. 9: 255–267), 1938.

Wierbicki, E., *et al.,* Food Technology, (8): 506–511, 1954.

vaccinating twice with an oil adjuvant vaccine offers 99 percent protection, the proposed rule does not require any specific vaccine or number of vaccinations. The commenter questioned whether changes in Uruguay's choice of vaccine or the number of doses would affect the efficacy of the mitigation measure and affect the outcome of the risk assessment. The commenter also asked if we would change the import requirements and mitigation measures if Uruguay decides to stop vaccinating in the future.

Because Uruguay responded so quickly to the outbreak of FMD in April 2001, officials there did not have the opportunity to test different FMD vaccines to determine which was most effective. Uruguay used trivalent vaccines from Brazil and Paraguay and bivalent vaccines from Colombia and Argentina that had been approved and certified in their respective country of origin by the competent sanitary authority. In all cases, safety and efficacy tests used were those established by the regional reference agency, the Pan American FMD Center (PANAFTOSA). Once the outbreak was under control, however, Uruguay's Ministry of Livestock, Agriculture, and Fisheries, together with PANAFTOSA, conducted tests on a variety of vaccines in order to determine which would be most effective for use in the ongoing vaccination program. We have reviewed the results of these tests and have found Uruguay's choice of vaccine, which offered a protection level of 99.7 percent after revaccination, to be adequate and effective. We do not believe it is necessary to require the use of a particular vaccine in this rule, as it is unlikely that Uruguay will choose a less efficacious vaccine in the future. However, we will continue to monitor the situation and make any necessary adjustments to the mitigation measure requirements if any changes occur.

As stated in the site visit report, under Uruguayan law, cattle are not allowed to be moved until they have been vaccinated against FMD twice. All cattle that are moved within Uruguay are required to be accompanied by a certificate that contains information about the date, brand, and series of vaccine that was used. Because this dosage requirement is already in place, we do not believe it is necessary to add this requirement to the rule. We will continue to monitor the situation and will reassess the situation and the risk level if any changes in Uruguay's vaccination requirements occur.

One commenter, referring to the scenarios presented in the risk assessment, asked about the expected incursions of FMD using a scenario of over 100 undetected herds.

We believe the commenter has misinterpreted the scenarios presented in the risk assessment. First, we note that the risk assessment never states that the data refer to potential ''incursions'' of FMD. The results from the scenarios described in the risk assessment were derived from the negative binomial distribution, which calculates the number of years before the first importation of FMD-infected beef, not the first outbreak or case of FMD, from such imports. Second, the commenter appears to assume that we are comparing scenarios with a maximum of 35 undetected, infected herds versus a maximum of 62 undetected, infected herds. In our risk assessment, we developed two scenarios. The first scenario, which we believe is the most realistic, offers data for a situation involving between 1 and 35 undetected, infected herds. This scenario was run using a uniform distribution of values rather than point values, which means that every value within the range of 1 to 35 has an equal likelihood of occurrence. The second scenario, which we believe is less realistic but necessary in order to capture the full range of possible uncertainty, offers data for a situation involving between 1 and 62 undetected, infected herds, with a most likely value of 35 undetected, infected herds.

In order to reasonably evaluate a scenario for over 100 undetected, infected herds, we also had to present point value results at 35 and at 62 undetected herds. The results are presented in table 1, below. These results represent the number of years until the first importation of FMD-infected beef from Uruguay, not the first expected incursion of FMD.

TABLE 1.—RISK SCENARIO FOR OVER 100 UNDETECTED HERDS

	Point estimate of the number of infected and undetected herds		
	35	62	100
Mean number of years until the first importation of FMD-infected beef from Uruguay	10,500	5,900	3,700
Most likely number of years until the first importation of FMD-infected beef from Uruguay	6,200	550	510

The results show that for an average of 100 undetected, infected herds per year in Uruguay, the most likely number of years until the first importation of FMD-infected beef is 510. However, based on past history, we believe that it is likely that FMD would be detected before the number of undetected infected herds reached 100. Therefore, we do not believe that this risk scenario offers any realistic information about the risk of importing fresh (chilled or frozen) beef from Uruguay.

Serological Surveillance

One commenter noted that APHIS did not discuss FMD infection in feral species in Uruguay. The commenter asked if surveillance has been done in feral populations. Although the information available to us indicates that there is no surveillance of wildlife populations in Uruguay, we have no evidence that indicates that feral animal populations in Uruguay are infected with FMD. To our knowledge, infections of FMD in wildlife were not a factor in the spread of FMD, nor were wildlife populations reservoirs of infection in past outbreaks. We have concluded that authorities in Uruguay are conducting adequate surveillance for FMD to detect the disease if it were to be reintroduced into the country. While there was no specific information presented to show that susceptible feral animals in Uruguay are free of FMD, the active surveillance program includes domestic animals that may be exposed to feral animal populations.

One commenter inquired whether there were any results available from surveillance in susceptible species other than bovine. Uruguay has conducted surveillance of sheep, as discussed below. There has been no active surveillance of swine in Uruguay, partly because there are only approximately 300,000 pigs in the entire country. During the past outbreak, only 112 pigs were affected by FMD. Based on the small population of swine, combined with the fact that the FMD virus that was present in Uruguay affects

primarily cattle, and that swine react differently to FMD in general, we do not consider swine to be critical as the primary focus of serological surveillance.

One commenter asked whether the results of the sampling of sheep that was scheduled to be completed by May 2002 were available. A serological survey of the sheep population of Uruguay was conducted between May and August 2002. The survey was designed to detect virus activity in 1 percent of the sheep population and to identify sheep flocks with 5 percent or more infected sheep. Three groups were defined for sampling by geographical strata based on distance from the nearest FMD focus in previous outbreaks: Stratum I-less than 5 km, stratum II–5–10 km, and stratum III-greater than 10 km. Within each group, sheep operations were randomly selected in proportion to flock size.

The survey sampled 18,296 sheep from 340 flocks. Using the Virus Infection Associated Antigen (VIAA) test, the estimated seroprevalence for antibodies to the FMD virus was 0.16 percent. The results show a decline from a previous survey. By geographic area, the seroprevalence was 0.23 percent in stratum I, 0.08 percent in stratum II, and 0.04 percent in stratum III. A subsequent epidemiological investigation of the 20 seropositive animals concluded that the positive results were due to residual antibodies from exposure during the previous epidemic.

Because unvaccinated sheep were not involved in large numbers during the most recent outbreak of FMD, one commenter questioned the utility of using unvaccinated sheep as sentinels for the virus. We agree that sheep were not a major factor in the establishment and spread of FMD during the 2001 outbreak in Uruguay. In addition, the available evidence suggests that sheep may not be good sentinels for detecting the presence of clinical disease. However, the serological evidence provided by Uruguay indicates that sheep may serve as serological sentinels based on the data on seroconversion that were received during surveys conducted in 2001. Monitoring the fluctuations in the levels of antibodies that the sheep develop will give scientists and veterinarians a warning about the presence of FMD.

One commenter asked if serosampling since February 2002 has continued to show a decline in prevalence. Serological sampling of the cattle population in November 2002 indicated a decline in FMD prevalence compared to previous surveys. As stated in the risk assessment, Uruguay conducted two serological surveys in 2001 and 2002 in the cattle population, using the 3ABC enzyme-linked immunosorbent assay (ELISA) to detect antibodies against FMD non-structural protein. The seroprevalence of FMD was estimated to be 9.26 percent in 2001 and 2.3 percent in February 2002.

Using the 3B ELISA test for non-structural antibodies to the FMD virus, the estimated seroprevalence in November 2002 was 1.98 percent. Sera positive on the 3B ELISA were retested using the 3A ELISA in order to increase specificity, resulting in an adjusted seroprevalence estimate of 0.65 percent. This indicates that there is a declining trend of non-structural antibodies.

One commenter asked whether the USDA had looked at the test kit variation for the 3ABC ELISA test. We have evaluated test results obtained by Uruguay in their serological survey conducted in February 2002 in cattle. The data were obtained using two different 3ABC ELISA kits (United Biomedical Incorporated (UBI) and Pirbright 3ABC ELISA kits) and the Virus Infection Associated Antigen (VIAA) test. The types of tests and the results obtained during that survey are provided in table 2. The FMD prevalence estimates provided by Uruguay were based on results obtained using the UBI kit. After retesting of serum samples using the Pirbright 3ABC ELISA kit and the VIAA test, the data showed a three-fold reduction in the number of positive samples. However, the number of positive samples in the two additional tests were quite comparable. In order to maximize the risk estimates, APHIS used the prevalence estimates that were obtained using the UBI kit in the quantitative risk assessment.

TABLE 2.—SEROLOGICAL SAMPLING IN CATTLE IN URUGUAY 2002

Regions*	Holdings sampled	Holdings with positive sera—		
		UBI	Pirbright 3ABC	VIAA
Stratum I (< 5 km)	59	18	7	10
Stratum II (5–10 km)	65	16	6	5
Stratum III (>10 km)	75	15	5	2

*Regions for sampling were established based on their distance from the nearest FMD focus in the previous outbreaks.

One commenter noted that the site visit report states that ''[a]lthough the team felt that positive 3ABC ELISA tests may not be a result of field virus, that possibility cannot be totally excluded,'' and asked if more serological surveys will be done to exclude the possibility of circulating FMD virus.

We will continue to monitor the situation in Uruguay and will evaluate the results of serological surveys being conducted by Uruguay. We evaluated data from the two previous serological surveys conducted in 2001 and 2002 and concluded that serological surveillance and sampling schemes were adequate. In addition, APHIS concluded that the official national laboratory in Montevideo, which is the only laboratory approved to carry out FMD serological testing in Uruguay, has the capacity to run valid serological tests for FMD.

Based on the serological data provided by Uruguay, APHIS could not exclude the possibility that positive 3ABC ELISA tests are due to field virus. APHIS believes that this possibility cannot be excluded under any circumstances. In the July 2002 site visit report, APHIS mentioned that the positive results were likely due to the use of partially purified or unpurified vaccines, or to false-positive tests for the following reasons: (1) There was a declining pattern of FMD prevalence in the two surveys, which indicates that the positive response may not be due to infection; (2) the distribution of the positive holdings was quite comparable among the three different geographical regions (strata I, II, and III), which suggested false-positive tests since both strata II and III did not include any farms with registered FMD cases at any time during the outbreaks; and (3) when the sera were further processed by the central laboratory using 3ABC ELISA kits from a different source, in addition to the VIAA test, the number of positives was markedly reduced (see

table 2). The 101 total positive sera from the UBI kit were distributed among 49 different holdings that were scattered all over the country with no geographical or epidemiological relationship. We used the higher prevalence estimates based on 101 positive animals in our quantitative risk assessment in order to maximize the risk estimate.

One commenter asked what the future follow-up procedures for serosamples found to be positive using the 3ABC ELISA test will be and how we will ensure that 3ABC positive serology cases trigger follow-up testing for virus isolation by OIE approved methods.

In bovine sampling, Uruguay has been using the UBI ELISA test kit to identify 3B FMD non-structural antibodies. According to the manufacturer's recommendation, the ELISA test for the detection of 3A FMD non-structural antibodies is used as a confirmatory test. As stated in the site visit report, this testing and retesting strategy has been followed in Uruguay. In cases in which positive animals persist after the two rounds of tests, Uruguayan officials proceed with clinical investigation of the susceptible species in order to confirm or reject any suspected presence of the disease.

One commenter asked what the scientific basis was for the statement in the risk assessment that fully protected animals are unlikely to become viremic. According to the commenter, a 2002 Pirbright Laboratory study showed that vaccinated swine will become viremic and shed virus despite their lack of clinical signs.

First, we note that our risk assessment was conducted specifically to determine the risk level associated with beef from Uruguay. The word ''animal'' throughout the risk assessment refers exclusively to the bovine species from which beef is derived.

Second, based on several different transmission studies,[6] a case can be made for the lack of significant viremia in vaccinated cattle. The findings of these studies suggest that higher immunity levels due to multiple applications of FMD vaccine or increased duration between vaccination and virus challenge result in reduced virus production or none at all.

We also note that swine respond differently than cattle do to the FMD virus. The study cited by the commenter relates to vaccinated swine, which were not largely affected by the strain of the virus that was present in Uruguay, and is not pertinent to this rule. However, we welcome any additional information or data that the commenter can provide, and we will review all such information as appropriate.

One commenter asked whether we had reviewed Uruguay's surveillance data to determine if Uruguay satisfies the OIE's ''FMD-free with vaccination'' status requirements. Although we do take international standards into consideration, we conduct independent risk assessments using our own stringent criteria as detailed previously. This rule relates to determining what mitigation measures would be effective in protecting the United States from the introduction of FMD in light of the fact that Uruguay does vaccinate, and this rule does not address whether Uruguay can be considered FMD-free with vaccination according to OIE standards.

One commenter expressed concern that FMD is often carried in animals that show no signs of disease until they are under stress. The commenter wanted to know how we would protect against this. We note that animals that show signs of FMD when under stress will do so as a consequence of viremia. All of our mitigation measures specifically target viremic animals.

General Questions

Several commenters expressed concern that the last outbreak of FMD was too recent for Uruguay to be considered a safe source of imported beef. Two of these commenters stated that we should require a longer disease-free waiting period, ranging from 3 to 5 years, and one commenter suggested that we conduct periodic, independent verification of the disease-free status of Uruguay during that waiting period. One commenter stated that we need to evaluate and take into consideration both the FMD status of Uruguay and the longevity of its disease-free status.

Our risk assessment process is thorough and rigorous. All of the evidence in our risk assessment and site visit report indicates that Uruguay is effectively controlling FMD and has established adequate precautions, including border and movement controls and surveillance and vaccination programs, to ensure the safety of the commodity it wishes to export. Further, the mitigation measures that we require offer additional protection against the introduction of FMD into the United States from the importation of fresh (chilled or frozen) beef from Uruguay. We do not consider a 3 to 5 year disease-free waiting period to be either necessary or required by international requirements or standards.

One commenter noted that vampire bats are common in South America and asked if we had taken into account the fact that they could spread disease among cattle and how we planned to protect against this possibility. The commenter did not provide data to support the hypothesis that vampire bats are a transmission issue for FMD in Uruguay, and we are unaware of any such evidence.

One commenter noted that some of the supporting documents that accompanied the proposed rule were made available only in Spanish. The commenter stated that expenses to the reader are incurred when countries do not supply us with translated documents.

Although we were unable to identify the supporting documentation to which the commenter referred, the regulations in 9 CFR 92.2, which relate to applications by regions for recognition of the animal health status of that region, require that countries supply supporting documents in English. While we occasionally post supporting documents in a foreign language, these are usually documents obtained and discussed during site visits. In these instances, oral translation was provided to the site visit team, but no English language version of the document was made available. We have not always required written translations of such documents since the information in them, which was presented orally during the site visit, is included in the site visit report.

Two commenters stated that Uruguay should establish agreements with its neighboring countries and trading partners to ensure that they receive timely information about the presence of FMD in those countries. We agree that FMD in South America presents a regional challenge and that an effective regional approach is necessary to reduce the risk of disease spread from the region. Such a regional approach does exist. As noted in our site visit report, Uruguay, Argentina, and Brazil participate in the Cuenca del Plata FMD program under the auspices of PANAFTOSA. The main objective of the Cuenca del Plata program is to eradicate FMD with a regional, harmonized approach. Shortly after FMD outbreaks in 2001 in Argentina, Uruguay, and

[6] Barnett, P.V. and Carabin, H., A review of emergency foot-and-mouth disease (FMD) vaccines. Vaccine, (2002), 20:1505–1514.

Doel, T.R., Natural and vaccine-induced immunity to foot-and-mouth disease: the prospect for improved vaccines. Revue Scientifique et Technique, OIE, (1996), 15(3):883–911.

Donaldson, A.I. and Kitching, R.P., Transmission of foot-and-mouth disease by vaccinated cattle following natural challenge. Research in Veterinary Science, (1989), 46:9–14.

Sellers, R.F., Herniman, K.A.J., and Gumm, I.D., The airborne dispersal of foot-and-mouth virus from vaccinated and recovered pigs, cattle and sheep after exposure to infection. Research in Veterinary Science, (1977), 23:70–75.

Brazil, PANAFTOSA conducted inspection visits in the three countries and issued recommendations to strengthen and improve the existing FMD programs.

In addition, Uruguay has reviewed its own FMD strategy and has increased the authority of local offices in border areas, improved communication between local offices, developed a communication and education program for producers, and established a National Honorary Animal Health Commission with the participation of producers and both private and official veterinarians. The regional situation has greatly improved since 2001.

It is evident that Uruguay's government is committed to strengthening and improving its information systems for FMD surveillance and eradication in the region. Uruguay is continually reviewing and improving its regional coordination agreements. As a matter of national policy, Uruguay is coordinating with neighboring countries to establish common strategies for combating FMD and for direct information exchange between both official and private sectors.

We carefully considered the regional situation as an integral part of assessing Uruguay's FMD status, and we are continually monitoring the FMD situation in South America. We believe that Uruguay, Argentina, and Brazil have an effective cooperative, regional approach to FMD surveillance and control programs, and that each of these countries is committed to transparency and to collaboration in controlling and eradicating FMD.

A few commenters asked what guarantee we have that FMD has been eradicated in Uruguay. As noted in our site visit report, we have no evidence of the presence of the FMD virus in Uruguay, and have concluded that Uruguay has the ability to detect, control, and respond to FMD outbreaks in an effective way. The mitigation measures that we have put in place protect against the introduction of FMD into the United States.

A few commenters expressed concern that Uruguay is not able to determine where every beef animal is located or to confirm whether wild cattle are pastured on the same ranches with domestic cattle or that every herd is FMD-free. All cattle in Uruguay are identified with tags for movement that indicate the farm and herd of origin. All shipments of cattle must be accompanied by certificates that indicate that each animal has been vaccinated twice, and information about the date, brand, and series of vaccine that was used must also be on the certificate. In addition, Uruguay's ongoing surveillance program, combined with all of the movement control measures, provide adequate levels of surveillance for FMD in herds in Uruguay. Also, international trade agreements entered into by the United States provide that we should not require more of our trading partners than we carry out ourselves. The United States does not have a system that allows us to determine where every beef animal is located.

One commenter asked what guarantee we have that the mitigating measures are effective. The scientific literature supporting the efficacy of the mitigation measures such as the requirement that carcasses reach a pH level of 5.8 or below and the requirement that all bones, major lymph nodes, and blood clots be removed, is cited in the risk assessment. In addition, these measures comply with or exceed international standards for importing fresh (chilled or frozen) beef from countries that vaccinate against FMD. The OIE prescribes that the meat reach a pH level below 6.0 during the first 24 hours of maturation. Our requirement of a pH level of 5.8 or below provides a margin of safety and ensures the complete inactivation of the FMD virus.

One commenter requested that we provide details about the FSIS export plant approval process, Hazard Analysis and Critical Control Point (HACCP) related equivalency, and resampling procedures used to verify microbiological and residue requirements monitored upon arrival in the United States.

The FSIS regulations related to imported products are found in 9 CFR part 327. In those regulations, § 327.2(a)(2)(i) requires foreign countries to have a system of meat inspection that provides standards equivalent to those of the Federal system of meat inspection in the United States in areas that include, but are not limited to, ultimate control and supervision by the national government; the assignment of competent, qualified inspectors; and inspection, sanitation, quality, species verification, and residue standards.

The requirement listed in § 327.2(a)(2)(ii)(H) states that the foreign country must have an HACCP system as described in 9 CFR part 417. The regulations in § 327.2(a)(3) require a responsible official of the foreign meat inspection system to certify processing plants as eligible to participate in an export program according to all FSIS regulations contained within 9 CFR part 327. Sections 327.5 and 327.6 list the regulations and instructions related to importer applications for inspection of products for entry and related to reinspection of imported products. The actual procedures that FSIS uses for sampling and reinspection are detailed in that agency's Import Manual of Procedures. Information about FSIS requirements, procedures, and regulations can also be obtained on the Internet at *http://www.fsis.usda.gov.*

One commenter asked whether Uruguay's bovine spongiform encephalopathy (BSE) safeguarding system is equivalent to that of the United States. Although the intent of the proposal was to address the risk of importing fresh beef from Uruguay in the absence of other diseases, not to assess the risk of BSE in Uruguay, it should be noted that there is no evidence of which we are aware that BSE is a concern in Uruguay. Canada has evaluated Uruguay and found it to be low risk for BSE. Through our tricountry agreement with Canada and Mexico, we accept Canada's evaluation for our purposes. Furthermore, Uruguay has had minimal, if any, imports from Europe, and therefore minimal potential exposure to BSE. Additionally, regulations are set forth in § 94.18 of the regulations to guard against the introduction of BSE into the United States. We will continue to monitor the health status of Uruguay, and will reassess the situation if we determine that BSE has become a cause for concern with respect to Uruguay.

A few commenters asked how we will ensure that all biologicals, chemotherapeutics, extra-label usage, and pesticides in raw feed production are used under an approval system equivalent to ours. The issues raised by the commenters are beyond the scope of this rulemaking and deal primarily with products and practices that are under the purview of the FSIS and FDA and outside of our regulatory authority.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule with the changes discussed in this document.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. Immediate implementation of this rule is warranted to relieve certain restrictions on the importation of fresh (chilled or frozen) beef from Uruguay that are no longer necessary. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be

effective upon publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule amends the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from Uruguay. Based on the evidence documented in our recent risk assessment, we believe that fresh (chilled or frozen) beef can be safely imported from Uruguay provided certain conditions are met. This action provides for the importation of beef from Uruguay into the United States while continuing to protect the United States against the introduction of FMD.

This rule reopens the U.S. market to Uruguayan beef producers. Beef producers and importers in the United States should not experience any notable economic effects as a result of these changes because the United States has imported only a small amount of beef from Uruguay in the past (table 3).

TABLE 3.—VALUE OF U.S. SUPPLY AND IMPORTS OF FRESH (CHILLED OR FROZEN) BEEF AND URUGUAY'S SHARE

Year	U.S. imports from Uruguay	Total U.S. imports		U.S. supply (domestic production + imports − exports)	
	(In millions)	(In millions)	Uruguay's share	(In millions)	Uruguay's share
1997	$37.5	$1,407.9	2.7%	$22,941	0.2%
1998	29.2	1,609.8	1.8%	23,184	0.1%
1999	43.5	1,907.7	2.3%	23,846	0.2%
2000	40.9	2,221.0	1.8%	24,000	0.2%

Sources: Imports and Exports: U.S. Department of Commerce, Bureau of the Census, as reported by the World Trade Atlas. Domestic production: Calculated from quantities reported in Table 7–72 of Agricultural Statistics 2000, with a wholesale price for the 3 years conservatively approximated at $90 per hundredweight.

Uruguay's share in the value of U.S. imports of fresh (chilled or frozen) beef has been very small. From 1997 to 2000, Uruguayan exports accounted for only 1.8 to 2.7 percent of total U.S. imports of fresh (chilled or frozen) beef. During the same period, imports from Uruguay accounted for 0.2 percent or less of the value of the U.S. supply (domestic production plus imports minus exports) of fresh (chilled or frozen) beef.

Impact on Small Entities

According to the Small Business Administration's (SBA) size standards, beef cattle ranches and farms having $750,000 or less in annual revenue, and cattle feedlots having $1,500,000 or less in annual revenue, are considered small entities. The number of farms and ranches with beef herds in the United States in 1997 was reported to be 766,991, and 99.8 percent of these beef farms could be categorized as small according to the SBA's criteria.[7] It is impossible to determine from published data how many U.S. cattle feedlots could be categorized as small according to the SBA's criteria. Industry analysts suggest that feedlots with a capacity of roughly 1,000 head of cattle would have annual revenues of approximately $1,500,000. In 2000, roughly 18 percent (2,508) of cattle feedlots in the United States would have been considered small by SBA standards.[8]

Although this rule could potentially affect a large number of small beef farms and a relatively small number of small feedlots because it allows Uruguayan beef into the U.S. market, it is not expected to have a significant economic effect on these entities because the import volumes involved are low.

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

Executive Order 12988

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

Paperwork Reduction Act

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

[7] USDA, National Agricultural Statistics Service, 1997, Census of Agriculture-United States Data table 28, page 32.

[8] Unpublished National Agricultural Statistics Service data, from *Changes in the U.S. Feedlot Industry 1994–1999,* USDA/APHIS/NAHMS, August 2000.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 94.1, paragraph (b)(2) and the introductory text of paragraph (d) are revised and a new paragraph (b)(4) is added to read as follows:

§ 94.1 Regions where rinderpest or foot-and-mouth disease exists; importations prohibited.

* * * * *

(b) * * *

(2) Except as provided in paragraph (d) of this section for fresh (chilled or frozen) meat of ruminants or swine that is otherwise eligible for importation under this part but that enters a port or otherwise transits a region where

rinderpest or foot-and-mouth disease exists; and

* * * * *

(4) Except as provided in § 94.21 for fresh (chilled or frozen) beef from Uruguay.

* * * * *

(d) Except as otherwise provided in this part, fresh (chilled or frozen) meat of ruminants or swine raised and slaughtered in a region free of foot-and-mouth disease and rinderpest, as designated in paragraph (a)(2) of this section, and fresh (chilled or frozen) beef exported from Uruguay in accordance with § 94.21, which during shipment to the United States enters a port or otherwise transits a region where rinderpest or foot-and-mouth disease exists may be imported provided that all of the following conditions are met:

* * * * *

■ 3. A new § 94.21 is added to read as follows:

§ 94.21 Restrictions on importation of beef from Uruguay.

Notwithstanding any other provisions of this part, fresh (chilled or frozen) beef from Uruguay may be exported to the United States under the following conditions:

(a) The meat is beef from bovines that have been born, raised, and slaughtered in Uruguay.

(b) Foot-and-mouth disease has not been diagnosed in Uruguay within the previous 12 months.

(c) The beef came from bovines that originated from premises where foot-and-mouth disease has not been present during the lifetime of any bovines slaughtered for the export of beef to the United States.

(d) The beef came from bovines that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.

(e) The beef came from bovines that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.

(f) The beef consists only of bovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter. Bovine parts that may not be imported include all parts of bovine heads, feet, hump, hooves, and internal organs.

(g) All bone and visually identifiable blood clots and lymphoid tissue have been removed from the beef.

(h) The beef has not been in contact with meat from regions other than those listed in § 94.1(a)(2).

(i) The beef came from bovine carcasses that were allowed to maturate at 40 to 50° F (4 to 10° C) for a minimum of 36 hours after slaughter and that reached a pH of 5.8 or less in the loin muscle at the end of the maturation period. Measurements for pH must be taken at the middle of both *longissimus dorsi* muscles. Any carcass in which the pH does not reach 5.8 or less may be allowed to maturate an additional 24 hours and be retested, and, if the carcass still has not reached a pH of 5.8 or less after 60 hours, the meat from the carcass may not be exported to the United States.

(j) An authorized veterinary official of the Government of Uruguay certifies on the foreign meat inspection certificate that the above conditions have been met.

(k) The establishment in which the bovines are slaughtered allows periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative.

Done in Washington, DC, this 21st day of May 2003.

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–13248 Filed 5–28–03; 8:45 am]

BILLING CODE 3410–34–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 791

Rules of NCUA Board Procedure; Promulgation of NCUA Rules and Regulations; Public Observance of NCUA Board Meetings

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: This final rule, Interpretive Ruling and Policy Statement (IRPS) 03–2, amends the Regulatory Flexibility Act provisions of NCUA's IRPS 87–2, Developing and Reviewing Government Regulations. The Regulatory Flexibility Act generally requires federal agencies to prepare analyses to describe the impact of proposed and final rules on small entities. Since 1981, the NCUA has defined small entity in this context to mean those credit unions with less than one million dollars in assets. This final rule redefines small entity to mean those credit unions with less than ten million dollars in assets. In addition, the rule amplifies a provision regarding NCUA's policy of reviewing all existing regulations every three years by stating that one-third of existing regulations will be reviewed each year and the public will receive notice of those regulations under review. The rule also updates IRPS 87–2 with a reference to the U.S. Small Business Administration guidance on implementation of the Regulatory Flexibility Act and to a Small Business Regulatory Enforcement Fairness Act requirement for publication of the factual basis supporting any certification that a particular rule will not have a significant economic impact on a substantial number of small entities.

DATES: This rule is effective June 30, 2003.

FOR FURTHER INFORMATION CONTACT: Paul M. Peterson, Staff Attorney, Office of General Counsel, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428 or telephone: (703) 518–6555.

SUPPLEMENTARY INFORMATION:

A. Background

In 1981, the NCUA defined small credit union for purposes of the Regulatory Flexibility Act (RFA), Pub. L. 96–354, as any credit union having less than one million dollars in assets. NCUA IRPS 81–4, 46 FR 29248, June 1, 1981. IRPS 87–2 superseded IRPS 81–4 but continued the definition of small credit unions for purposes of the RFA as those with less than one million dollars in assets. 52 FR 35231, 35232, September 8, 1987. IRPS 87–2 is incorporated by reference into NCUA's current rule governing the promulgation of regulations. 12 CFR 791.8(a).

The Board believes that NCUA's current definition of small credit union as one with less than one million dollars in assets, adopted in 1981, is now outdated. On November 21, 2002, the Board issued a Notice of Proposed Rulemaking (NPRM) to amend the definition of small credit union in IRPS 87–2. 67 FR 72113, December 4, 2002. The Board proposed to change the qualifying asset size for a small credit union from less than one million dollars in assets to less than ten million dollars in assets. This final rule adopts the proposed rule's definition of small credit union.

As discussed in the NPRM, the RFA is intended in part to encourage federal agencies to give special attention when making rules to the inability of smaller entities to handle incremental compliance burdens created by new rules. Credit unions with ten or more million dollars in assets have staff that may devote some of their time to compliance issues and incremental compliance burdens, but credit unions with significantly less than ten million

dollars in assets may be forced to seek and pay for outside assistance when addressing incremental compliance burdens. Accordingly, credit unions with more than ten million dollars in assets should be able to handle incremental compliance burdens more easily than credit unions with less than ten million dollars in assets.

A definition of small credit union as one with less than ten million dollars in assets is also consistent with recent statutes and NCUA regulations providing credit unions with regulatory compliance relief. For example, in 1998 Congress amended the Federal Credit Union Act to require that credit unions follow generally accepted accounting principles, but at the same time excused credit unions with less than ten million dollars in assets under a *de minimus* exception. 12 U.S.C. 1782(a)(6)(C)(i), (iii). Another 1998 amendment to the FCUA requires NCUA to provide ''small credit unions,'' defined as those under ten million dollars in assets, with special assistance in meeting prompt corrective action requirements. 12 U.S.C. 1790d(f)(2). Finally, NCUA regulations provide that federally insured credit unions with less than ten million dollars in assets may file a short form call report in the spring and fall. 12 CFR 741.6(a).

The Board also notes that by increasing the threshold from one million dollars in assets to ten million dollars in assets the percentage of federally insured credit unions considered to be small will return to a percentage much closer to the percentage captured by the size standard first adopted in 1981.

The Board also proposed to add a provision in Section IV of IRPS 87–2 stating how NCUA carries out the policy of reviewing all existing regulations every three years and providing for notice to the public of that portion of the regulations that are under review each year. The final rule includes this provision.

This final rule includes a reference to *The Regulatory Flexibility Act: An Implementation Guide for Federal Agencies* (U.S. Small Business Administration, November, 2002) and requires NCUA staff to consult it when interpreting and implementing the requirements of the RFA. While a regulatory flexibility analysis is unnecessary if the Board certifies a regulation will not have a significant economic effect on a substantial number of small entities, the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires that agencies publish a statement ''providing the factual basis for'' any such certification in the **Federal Register**. Pub. L. 104–121, 5 U.S.C. 605(b). IRPS 87–2 has provided that the certification will be published with a statement ''explaining'' the certification. This final rule replaces ''explaining'' with ''providing the factual basis for.''

B. Summary of Comments

NCUA received seventeen comment letters on the proposed rule: two from federal credit unions, five from state credit unions, eight from credit union trade organizations, one from a bank trade organization, and one from the National Association of State Credit Union Supervisors.

All of the commenters expressed support for changing the definition of small credit union to include more credit unions in the definition, with most of the commenters agreeing that small credit union should be redefined as a credit union with less than ten million dollars in assets. In addition, all the commenters who addressed the proposal to provide public notice of those regulations NCUA is reviewing each year as part of its three-year rolling review expressed approval for that notice.

Comments on the Asset Size Threshold for Small Credit Unions

The eleven commenters who supported a ten million dollar threshold generally noted it was consistent with current statutory definitions of small credit union and with the effects of inflationary changes since 1981 and would result in a reasonable percentage of all credit unions (about 52%) being considered small. One commenter supported the ten million dollar threshold but stated it should not be greater than ten million.

Five commenters thought the asset threshold should be greater than ten million dollars. Of these commenters, two thought the threshold should be 20 million dollars, one thought it should be 25 million dollars, one thought it should be at least 50 million dollars, and another thought it should be 100 million dollars.

The commenters supporting thresholds of 20 and 25 million dollars note that the percentage of credit unions under one million dollars in assets in 1981, when the current definition of small credit union was established, was roughly 63% of all credit unions, and that the percentages of credit unions today under 20 million and 25 million dollars (66% and 70%, respectively) are close to 63%. One of these commenters also states that ''credit unions with 20 million dollars in assets, although slightly larger than those with ten million dollars in assets, typically still do not have the resources to devote staff time solely to compliance issues.''

The commenter who supported a 50 million dollar threshold stated that: (1) only 10% of credit unions under 20 million dollars in assets have ''paid compliance directors,'' (2) only 16% of credit unions under 50 million dollars in assets have such directors, and (3) only 31% of credit unions between 50 million and 100 million dollars in assets have such directors. This commenter also noted that the federal banking regulators and the U.S. Small Business Administration generally set the RFA's small entity threshold for their regulated financial entities at 150 million dollars in assets. The commenter who supported a 100 million dollar threshold also made similar comments.

The Board appreciates the comments of those who supported a more expansive definition of small credit union but notes that a majority of the commenters supported the proposed definition. Further, the proposed is consistent with other statutory uses of the term small credit union while more expansive definitions would not be. In addition, while credit unions with ten million dollars or more in assets may not have staff devoted exclusively to compliance issues, the Board concludes, as noted in the NPRM, they are likely to have some staff that can devote time to compliance. This analysis is appropriate in light of the legislative history of the RFA discussed in the NPRM. Accordingly, the Board has decided to adopt the definition of small credit union from the proposed rule.

Miscellaneous Comments on the Definition of Small Credit Union and Applicability of the RFA

A few commenters thought the asset threshold for small credit unions should be adjusted periodically: one suggested revisiting the threshold each year; two suggested tying it to inflation; and another suggested that NCUA should reset the threshold yearly by declaring as small that group of the smallest credit unions whose combined assets equal 10% of the aggregate assets of all credit unions. The Board believes that annual adjustment is unnecessary and might have undesirable consequences. For example, with inflation levels likely to remain low for the foreseeable future, the Board does not think the threshold needs to be revisited each year. In addition, the rulemaking process for particular rules often spans more than one calendar year, and it would be difficult and confusing to change the definition for rules in progress every year. Finally, the use of a fixed, round

number makes it easier to assess which credit unions are small and to explain how NCUA is applying the RFA analysis in a particular rulemaking. The Board will revisit the definition of small credit union as necessary in the future.

One commenter thought that, for rules in which the NCUA determines the RFA does not apply, the NCUA should publish details of its determination. As discussed above, this final rule amends IRPS 87–2 to reflect the SBREFA requirement that NCUA publish the factual basis for each certification in the **Federal Register**.

Two commenters thought the NCUA should go beyond the requirements of the RFA and should undertake and publish a detailed analysis of the economic impact of each rule on all credit unions, regardless of asset size. The Board does not believe an RFA-type analysis is needed for every rulemaking, but notes that it is NCUA's longstanding policy, as stated in IRPS 87–2, that it will impose only minimum required burdens on credit unions.

Miscellaneous Comments About Public Notice of Regulations Under NCUA Review

One commenter suggested that each year at its December meeting the Board announce which regulations would be reviewed by the NCUA Office of General Counsel in the coming year and which provisions in those regulations were specifically under consideration for change. The commenter thought this notice should be published both on the agency's website and in the **Federal Register**. Another commenter wanted the notice of regulations under review published twice a year and a designated contact point at NCUA for all questions and comments about a regulation under review.

The Board will publish notice of the regulations under rolling review in a particular year far enough in advance of the review to give interested parties a meaningful opportunity for input. The notice may be published on NCUA's website, in the **Federal Register**, or in other appropriate media as determined by NCUA. NCUA also publishes a semi-annual regulatory agenda in the **Federal Register** as part of the federal government's Unified Agenda of Federal Regulatory and Deregulatory Actions. That agenda, generally published each November and May, includes contact information and a description of rules that are in process or on which regulatory action is anticipated for the next 12 months.

One commenter thought that NCUA should add the following statement to IRPS 87–2: ''Nothing in the Office of General Counsel's rolling review schedule prohibits the review of existing regulations ahead of schedule.'' While the Board believes that this is a true statement, the Board does not believe it need be added to IRPS 87–2.

Other Miscellaneous Comments

Two commenters thought the definition of small credit union in the Small Credit Union Program (SCUP) should be changed to correlate with the RFA definition. Another commenter stated the NCUA should also provide a definition of large credit unions. Since this rule applies only to NCUA rulemaking and the requirements of the RFA and does not affect the SCUP or large credit unions, these two issues are not addressed in the final rule.

Regulatory Procedures

Regulatory Flexibility Act

The RFA requires the NCUA to prepare an analysis to describe any significant economic effect any regulation may have on a substantial number of small credit unions, currently meaning those under one million dollars in assets. This final rule, when effective, will change the definition of small credit union to increase the number of credit unions receiving the procedural benefits of the RFA and will provide notice to the public and opportunity to comment on regulations under internal review. This final rule is procedural in nature and will not have any ascertainable economic impact on credit unions. Accordingly, the NCUA Board has determined and certifies that the final rule will not have a significant economic impact on a substantial number of small credit unions. No regulatory flexibility analysis is required.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. This final rule will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined that this rule does not constitute a policy that has federalism implications for purposes of the executive order.

Paperwork Reduction Act

NCUA has determined that the final rule does not increase paperwork requirements under the Paperwork Reduction Act of 1995 and regulations of the Office of Management and Budget.

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

The NCUA has determined that this final rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Pub. L. 105–277, 112 Stat. 2681 (1998).

Small Business Regulatory Enforcement Fairness Act

The SBREFA provides for congressional review of agency rules. A reporting requirement is generally triggered in instances where NCUA issues a final rule as defined by Section 551 of the Administrative Procedure Act. 5 U.S.C. 551. Rules relating to management, personnel, or agency procedure or practice that do not substantially affect the rights or obligations of non-agency parties are exempt from congressional review. 5 U.S.C. 804(3). The NCUA Board has determined that this final rule, which deals with agency procedures and does not substantially affect the rights or obligations of non-agency parties, is exempt from congressional review.

List of Subjects in 12 CFR Part 790

Organization and functions (government agencies).

By the National Credit Union Administration Board on May 22, 2003.

Becky Baker,

Secretary of the Board.

Interpretative Ruling and Policy Statement 03–2, Developing and Reviewing Government Regulations

For the reasons stated above, IRPS 03–2 amends IRPS 87–2 (52 FR 35231, September 18, 1987) by revising the second sentence in Section II, paragraph 2.; adding a sentence to the end of Section II, paragraph 2; revising the fourth sentence in Section II, paragraph 4; and adding a sentence to the end of Section IV to read as follows:

II. Procedures for the Development of Regulations

* * * * *

2. * * * Credit unions having less than ten million dollars in assets will be considered to be small entities. * * * In addition, NCUA staff will consult

applicable U.S. Small Business Administration guidance, including *The Regulatory Flexibility Act: An Implementation Guide for Federal Agencies,* when interpreting and implementing the requirements of the Regulatory Flexibility Act.

* * * * *

4. * * * The certification will be published in the **Federal Register** with the final rule, along with a statement providing the factual basis for such certification. * * *

* * * * *

IV. Review of Existing Regulations. * * * To accomplish a review every three years of all regulations, the Office of General Counsel will maintain a rolling review schedule that identifies one-third of existing regulations for review each year and will provide notice to the public of that portion of the regulations under review each year so the public may have an opportunity to comment.

* * * * *

Conforming Amendment to NCUA Regulations, 12 CFR Part 791

■ For the reasons stated above, amend 12 CFR part 791 as follows:

PART 791—RULES OF NCUA BOARD PROCEDURE; PROMULGATION OF NCUA RULES AND REGULATIONS; PUBLIC OBSERVATION OF NCUA BOARD MEETINGS

■ 1. The authority for part 791 continues to read as follows:

Authority: 12 U.S.C. 1766, 1789 and 5 U.S.C. 552b.

■ 2. Amend § 791.8 by revising paragraph (a) to read as follows:

§ 791.8 Promulgation of NCUA rules and regulations.

(a) NCUA's procedures for developing regulations are governed by the Administrative Procedure Act (5 U.S.C. 551 *et seq.*), the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), and NCUA's policies for the promulgation of rules and regulations as set forth in its Interpretive Ruling and Policy Statement 87–2 as amended by Interpretive Ruling and Policy Statement 03–2.

* * * * *

[FR Doc. 03–13342 Filed 5–28–03; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–290–AD; Amendment 39–13166; AD 2003–11–07]

RIN 2120–AA64

Airworthiness Directives; Israel Aircraft Industries, Ltd. Model 1121, 1121A, 1121B, 1123, 1124, and 1124A Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all Israel Aircraft Industries, Ltd. Model 1121, 1121A, 1121B, 1123, 1124, and 1124A series airplanes, that requires removing the existing oxygen shutoff valve and installing a new oxygen shutoff valve. This action is necessary to prevent rapid adiabatic compression within the oxygen line between the oxygen shutoff valve and the pressure regulator due to a shutoff valve that can be opened quickly, which could result in overheating of the oxygen system, and consequent fire in the cockpit. This action is intended to address the identified unsafe condition.

DATES: Effective July 3, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D25, Savannah, Georgia 31402. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all Israel Aircraft Industries, Ltd. Model 1121, 1121A, 1121B, 1123, 1124, and 1124A series airplanes was published in the **Federal Register** on February 21, 2003 (68 FR 8473). That action proposed to require removing the existing oxygen shutoff valve and installing a new oxygen shutoff valve.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the NPRM regarding that material.

Cost Impact

The FAA estimates that 300 Israel Aircraft Industries, Ltd. Model 1121, 1121A, 1121B, 1123, 1124, and 1124A series airplanes of U.S. registry will be affected by this AD, that it will take approximately 8 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $900 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $414,000, or $1,380 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions. The manufacturer may cover the cost of replacement parts associated with this AD, subject to warranty conditions. Manufacturer warranty remedies may

also be available for labor costs associated with this AD. As a result, the costs attributable to this AD may be less than stated above.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2003–11–07 Israel Aircraft Industries, Ltd.: Amendment 39–13166. Docket 2002–NM–290–AD.

Applicability: All Model 1121, 1121A, 1121B, 1123, 1124, and 1124A series airplanes; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent rapid adiabatic compression within the oxygen line between the oxygen shutoff valve and the pressure regulator due to a shutoff valve that can be opened quickly, which could result in overheating of the oxygen system, and consequent fire in the cockpit, accomplish the following:

Removal and Installation of Oxygen Shutoff Valve

(a) Within 250 flight hours after the effective date of this AD, remove the existing oxygen shutoff valve and install a new oxygen shutoff valve, per the Accomplishment Instructions of the applicable service bulletin specified in Table 1 of this AD, as follows:

TABLE 1.—SERVICE BULLETINS

For model—	Service bulletin—
1121, 1121A, 1121B series airplanes.	1121 Commodore Jet (Israel Aircraft Industries, Ltd.) Service Bulletin 1121–35–024, dated September 23, 2002.
1123 series airplanes	1123—Westwind (Israel Aircraft Industries, Ltd.) Service Bulletin 1123–35–048, dated September 23, 2002.
1124 and 1124A series airplanes.	1124—Westwind (Israel Aircraft Industries, Ltd.) Alert Service Bulletin 1124–35–137, dated September 23, 2002.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(d) The actions shall be done in accordance with the applicable service bulletin specified in Table 2 of this AD as follows:

TABLE 2.—SERVICE BULLETINS

Service Bulletin—
1121 Commodore Jet (Israel Aircraft Industries, Ltd.) Service Bulletin 1121–35–024, dated September 23, 2002.
1123-Westwind (Israel Aircraft Industries, Ltd.) Service Bulletin 1123–35–048, dated September 23, 2002.
1124-Westwind (Israel Aircraft Industries, Ltd.) Alert Service Bulletin 1124–35–137, dated September 23, 2002.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D25, Savannah, Georgia 31402. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Israeli airworthiness directive 35–02–10–12, dated October 17, 2002.

Effective Date

(e) This amendment becomes effective on July 3, 2003.

Issued in Renton, Washington, on May 19, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–12963 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–281–AD; Amendment 39–13152; AD 2003–10–07]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace LP Model Astra SPX and 1125 Westwind Astra Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Gulfstream Aerospace LP Model Astra SPX and 1125 Westwind Astra series airplanes, that requires removing the existing oxygen shutoff valve and installing a new oxygen shutoff valve. The actions specified by this AD are intended to prevent rapid adiabatic compression within the oxygen line between the oxygen shutoff valve and the pressure regulator due to a shutoff valve that can be opened quickly, which could result in overheating of the oxygen system and consequent fire in the cockpit. This action is intended to address the identified unsafe condition.

DATES: Effective July 3, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D25, Savannah, Georgia 31402. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Gulfstream Aerospace LP Model Astra SPX and 1125 Westwind Astra series airplanes was published in the **Federal Register** on February 21, 2003 (68 FR 8475). That action proposed to require removing the existing oxygen shutoff valve and installing a new oxygen shutoff valve.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received in response to the proposed rule or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the proposed AD regarding that material.

Cost Impact

The FAA estimates that 100 airplanes of U.S. registry will be affected by this AD, that it will take approximately 8 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $900 per airplane. Based on these figures, the cost impact of this AD on U.S. operators is estimated to be $138,000, or $1,380 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions. The manufacturer may cover the cost of replacement parts associated with this AD, subject to warranty conditions. Manufacturer warranty remedies may also be available for labor costs associated with this AD. As a result, the costs attributable to the AD may be less than stated above.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2003–10–07 Gulfstream Aerospace LP (Formerly Israel Aircraft Industries, Ltd.): Amendment 39–13152. Docket 2002–NM–281–AD.

Applicability: Model Astra SPX series airplanes having serial numbers 073 and 079

through 131 inclusive; and Model 1125 Westwind Astra series airplanes having serial numbers 004 though 072 inclusive, and 074 through 078 inclusive; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent rapid adiabatic compression within the oxygen line between the oxygen shutoff valve and the pressure regulator due to a shutoff valve that can be opened quickly, which could result in overheating of the oxygen system, and consequent fire in the cockpit, accomplish the following:

Removal and Installation of Oxygen Shutoff Valve

(a) Within 250 flight hours after the effective date of this AD, remove the existing oxygen shutoff valve and install a new oxygen shutoff valve, per the Accomplishment Instructions of Astra (Gulfstream Aerospace Corporation) Alert Service Bulletin 1125–35A–114, dated November 28, 2001, excluding Service Bulletin Certificate of Compliance.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(d) The actions must be done in accordance with Astra (Gulfstream Aerospace Corporation) Alert Service Bulletin 1125–35A–114, dated November 28, 2001, excluding Service Bulletin Certificate of Compliance. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D25, Savannah, Georgia 31402. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Israeli airworthiness directive 35–02–07–02, dated August 18, 2002.

Effective Date

(e) This amendment becomes effective on July 3, 2003.

Issued in Renton, Washington, on May 19, 2003.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–12962 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–399–AD; Amendment 39–13164; AD 2003–11–05]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Mystere-Falcon 900 and Falcon 900EX Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Dassault Model Mystere-Falcon 900 and Falcon 900EX series airplanes, that requires replacement of certain self-adhering soundproofing mats under the passenger consoles in the cabin, which are not sufficiently fire-retardant, with mats that are not self-adhering and are sufficiently fire-retardant. This action is necessary to prevent an uncontrolled fire in the cabin due to self-adhering soundproofing mats under the passenger consoles in the cabin, which are not sufficiently fire-retardant. This action is intended to address the identified unsafe condition.

DATES: Effective July 3, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Dassault Model Mystere-Falcon 900 and Falcon 900EX series airplanes was published in the **Federal Register** on March 3, 2003 (68 FR 9954). That action proposed to require replacement of certain self-adhering soundproofing mats under the passenger consoles in the cabin, which are not sufficiently fire-retardant, with mats that are not self-adhering and are sufficiently fire-retardant.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. The sole commenter supports the proposed AD.

Conclusion

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Changes to 14 CFR part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the NPRM regarding that material.

Cost Impact

The FAA estimates that 18 airplanes of U.S. registry will be affected by this AD, that it will take approximately 80 work hours per airplane to replace the mats, and that the average labor rate is $60 per work hour. Required parts will be provided by the manufacturer at no cost to the operators. Based on these figures, the cost impact of this AD on

U.S. operators is estimated to be $86,400, or $4,800 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2003–11–05 Dassault: Amendment 39–13164. Docket 2001–NM–399–AD.

Applicability: Model Mystere-Falcon 900 series airplanes, serial numbers 184 through 187 inclusive; and Model Falcon 900EX series airplanes, serial numbers 28 and 65 through 85 inclusive; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent an uncontrolled fire in the cabin due to self-adhering soundproofing mats under the passenger consoles in the cabin, which are not sufficiently fire-retardant, accomplish the following:

Mat Replacement

(a) Within seven months after the effective date of this AD, replace the self-adhering soundproofing mats with mats that are not self-adhering and are sufficiently fire-retardant, per paragraphs 2.A. through 2.D. of the Accomplishment Instructions of Dassault Service Bulletin F900–220 (for Model Mystere-Falcon 900 series airplanes), or F900EX–109 (for Model Falcon 900EX series airplanes); both dated June 29, 2001.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(d) The actions must be done in accordance with Dassault Service Bulletin F900–220, dated June 29, 2001; or Dassault Service Bulletin F900EX–109, dated June 29, 2001; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in French airworthiness directive 2001–267–035(B), dated June 27, 2001.

Effective Date

(e) This amendment becomes effective on July 3, 2003.

Issued in Renton, Washington, on May 20, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13121 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–03–AD; Amendment 39–13170; AD 2003–11–11]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model CL–600–2B19 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Bombardier Model CL–600–2B19 series airplanes, that currently requires repetitive eddy current inspections for cracking of the main landing gear (MLG) main fittings, and replacement with new or serviceable MLG main fittings if necessary. That AD also requires servicing the MLG shock struts; inspecting the MLG shock struts for nitrogen pressure, visible chrome dimension, and oil leakage; and performing corrective actions, if necessary. This amendment clarifies the applicability, adds certain repetitive inspections, reduces an initial inspection threshold, and removes a provision to extend the repetitive interval for the eddy current inspection.

This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified in this AD are intended to prevent failure of the MLG main fittings, which could result in collapse of the MLG upon landing.

DATES: Effective June 13, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 13, 2003.

Comments for inclusion in the Rules Docket must be received on or before June 30, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2003–NM–03–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-iarcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2003–NM–03–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in this AD may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Serge Napoleon, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7512; fax (516) 568–2716.

SUPPLEMENTARY INFORMATION: On October 22, 2001, the FAA issued airworthiness directive (AD) 2001–22–09, amendment 39–12488 (66 FR 54658, October 30, 2001). (A correction of that AD was published in the **Federal Register** on November 26, 2001 (66 FR 58931), and a second correction of that AD was published in the **Federal Register** on December 14, 2001 (66 FR 64739).) That AD is applicable to certain Bombardier Model CL–600–2B19 series airplanes and currently requires repetitive eddy current inspections for cracking of the main landing gear (MLG) main fittings, and replacement with new or serviceable MLG main fittings if necessary. That AD also requires servicing the MLG shock struts; inspecting the MLG shock struts for nitrogen pressure, visible chrome dimension, and oil leakage; and performing corrective actions, if necessary. The actions required by that AD are intended to prevent failure of the MLG main fittings, which could result in collapse of the MLG upon landing.

Background

As described in the notice of proposed rulemaking (NPRM) for AD 2001–22–09, three cases of premature failure of the MLG main fittings had been reported. The reports indicated that a circumferential crack was found on the MLG main fittings at the radius between the fitting cylinder area and the upper attachment lug for the shock strut. Further investigation indicated that, under certain conditions, an incorrectly serviced shock strut could lead to premature failure of the MLG main fittings.

Actions Since Issuance of Previous Rule

Since the issuance of AD 2001–22–09, Transport Canada Civil Aviation (TCCA), which is the airworthiness authority for Canada, has advised us of reports of another premature failure of the MLG main fittings. Subsequent laboratory examination has confirmed that the failure was at the identical location of the previously reported failures, except that this new incident resulted from a different failure mode.

Since the findings of this latest premature failure of the MLG main fittings, the following new service information has been issued:

The manufacturer issued Bombardier Alert Service Bulletin A601R–32–079, Revision ''E,'' dated September 12, 2002; including Appendix 1, Revision D, dated September 12, 2002; including Appendices 2 and 3, dated September 12, 2002. The revised service bulletin describes procedures for performing repetitive visual, eddy current, and fluorescent penetrant inspections of the MLG fittings, and replacement if necessary; servicing and inspecting the MLG shock struts; and performing corrective actions if necessary. The major changes to Bombardier Alert Service Bulletin A601R–32–079, Revision D, dated December 1, 2000, which is cited as the appropriate source of service information for accomplishment of AD 2001–22–09, include revising certain compliance times, adding repetitive fluorescent penetrant inspections, and removing the escalation of eddy current repetitive inspections. TCCA classified this service bulletin as mandatory.

TCCA has issued Canadian airworthiness directive CF–1999–32R2, dated September 19, 2002, to ensure the continued airworthiness of these airplanes in Canada. The Canadian airworthiness directive removes the procedure for escalation of the eddy current inspection interval and adds a detailed visual inspection of the MLG main fittings to supplement the eddy current inspection.

FAA's Conclusions

This airplane model is manufactured in Canada and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, TCCA has kept us informed of the situation described above. We have examined the findings of TCCA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD supersedes AD 2001–22–09 to continue to require certain requirements. Those requirements include performing repetitive eddy current inspections for cracking of the MLG main fittings; replacing with new or serviceable MLG main fittings if necessary; servicing the MLG shock struts; inspecting the MLG shock struts for nitrogen pressure, visible chrome dimension, and oil leakage; and performing corrective actions if necessary.

This AD clarifies the applicability, adds certain repetitive inspections, reduces an initial inspection threshold, and removes a provision to extend the repetitive interval for the eddy current inspection. The actions required by this AD must be accomplished per the referenced service bulletin, as described previously.

Clarification of Compliance Time Related to the Components

The compliance times specified in AD 2001–22–09 did not specify that the total flight cycles in paragraphs (a) and (b) of that AD are related to the MLG or shock struts, as applicable. To clarify this, we have revised certain paragraphs in this AD to specify that the compliance time is related to the components referenced in those paragraphs rather than to the airplane.

Clarification of Applicability

The Canadian airworthiness directive and Bombardier service bulletin both include Messier Dowty part numbers (P/Ns) for the MLG main fittings, which are comparable to the Bombardier P/Ns. For this reason, we have determined that it is necessary to clarify the applicability of this AD by referencing both Messier Dowty and Bombardier P/Ns.

Clarification of Replacement Requirement

AD 2001–22–09 requires replacement of any cracked MLG main fitting with a new or serviceable MLG, and the Bombardier service bulletin specifies such replacement with either an MLG or MLG fitting. However, in consonance with the Canadian airworthiness directive, this AD requires replacing any cracked MLG main fitting with a new or serviceable main fitting instead of replacing the entire MLG.

Explanation of Change to Existing AD

We have added paragraph (m)(2) of this AD to prohibit the use of alternative methods of compliance issued per paragraph (e) of AD 2001–22–09 that would have allowed escalation of the repetitive intervals for the eddy current inspections from 500 to 1,000 flight cycles.

Interim Action

This is considered to be interim action until final action is identified, at which time we may consider further rulemaking.

Determination of Rule's Effective Date

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

Comments Invited

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

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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

Commenters wishing us to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2003–NM–03–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by removing amendment 39–12488 (66 FR 54658, October 30, 2001), corrected at 66 FR 58931, November 26, 2001; and corrected at 66 FR 64739, December 14, 2001; and by adding a new airworthiness directive (AD), amendment 39–13170, to read as follows:

2003–11–11 Bombardier, Inc.: Amendment 39–13170. Docket 2003–NM–03–AD. Supersedes AD 2001–22–09, Amendment 39–12488.

Applicability: Model CL–600–2B19 series airplanes, certificated in any category, having serial numbers 7003 and subsequent, equipped with main landing gear (MLG) main fittings having part numbers (P/N) 601R85001–3 and 601R85001–4 (Messier Dowty, Inc. P/Ns 17064–101, 17064–102, 17064–103, and 17064–104).

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

been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

Note 2: Where there are differences between the referenced service bulletin and the AD, the AD prevails.

To prevent failure of the MLG main fittings, which could result in collapse of the MLG upon landing, accomplish the following:

Service Bulletin References

(a) Accomplishment of the inspections and servicing, as applicable, specified in paragraphs (c), (g), (h), and (i) of this AD, per Bombardier Alert Service Bulletin A601R–32–079, dated December 3, 1999; Revision ''A,'' dated January 7, 2000; Revision ''B,'' dated June 1, 2000; Revision ''C,'' dated October 26, 2000; or Revision ''D,'' dated December 1, 2000; prior to the effective date of this AD, is considered acceptable for compliance with the requirements of paragraphs (c), (g), (h), and (i) of this AD.

(b) The term ''service bulletin,'' as used in this AD, means the Accomplishment Instructions of Bombardier Alert Service Bulletin A601R–32–079, Revision ''E,'' dated September 12, 2002; including Appendix 1, Revision D, dated September 12, 2002; including Appendices 2 and 3, dated September 12, 2002.

Initial Eddy Current Inspection

(c) Perform an eddy current inspection to detect cracking of the MLG main fittings, per PART B of the service bulletin, at the earlier of the times specified in paragraph (c)(1) or (c)(2) of this AD.

(1) Prior to the accumulation of 1,500 total flight cycles on the MLG, or within 150 flight cycles after December 4, 2001 (the effective date of AD 2001–22–09, amendment 39–12488), whichever occurs later.

(2) Prior to the accumulation of 1,000 total flight cycles on the MLG, or within 150 flight cycles after the effective date of this AD, whichever occurs later.

Repetitive Eddy Current Inspections

(d) Repeat the eddy current inspection specified in paragraph (c) of this AD at the time specified in paragraph (d)(1), (d)(2), or (d)(3), as applicable, except as provided by paragraph (d)(4) of this AD, per PART B of the service bulletin.

(1) For airplanes on which the eddy current inspection required by paragraph (c) of this AD is accomplished after the effective date of this AD: Repeat the inspection at intervals not to exceed 500 flight cycles.

(2) For airplanes on which the repetitive eddy current inspection required by AD 2001–22–09, amendment 39–12488, has been accomplished, and on which the repetitive intervals have been increased per paragraph (e) of AD 2001–22–09 before the effective date of this AD: Repeat the inspection within 500 flight cycles after the effective date of this AD, or within 1,000 flight cycles since the last eddy current inspection, whichever occurs first, and thereafter at intervals not to exceed 500 flight cycles.

(3) For airplanes on which the repetitive eddy current inspection required by AD 2001–22–09 has been accomplished, and on which the repetitive intervals have not been increased per paragraph (e) of AD 2001–22–09 before the effective date of this AD: Repeat the eddy current inspection at intervals not to exceed 500 flight cycles.

(4) For airplanes on which an eddy current inspection has been accomplished to confirm the detailed inspection required by paragraph (j) of this AD: The next eddy current inspection must be done within 500 flight cycles following the last detailed inspection required by paragraph (j) of this AD, and thereafter at intervals not to exceed 500 flight cycles.

Corrective Actions

(e) If no cracking of the MLG main fittings is suspected during the next eddy current inspection required by paragraph (c) or (d) of this AD, but the paint has been removed: Prior to further flight, apply a new finish and install the harness clamp on the brake line with the bolt, washers, nut, and cotter pin; per PART B of the service bulletin.

(f) If any cracking of the MLG main fittings is found during any eddy current inspection required by paragraph (c) or (d) of this AD: Prior to further flight, replace any cracked MLG main fitting with a new or serviceable part per the service bulletin.

Servicing the Shock Struts

(g) Prior to the accumulation of 1,500 total flight cycles on the MLG shock struts, or within 500 flight cycles after December 4, 2001, whichever occurs later: Service (Oil and Nitrogen) the left and right MLG shock struts per PART C (for airplanes on the ground) or PART D (for airplanes on jacks) of the service bulletin.

Other Inspections

(h) Within 500 flight cycles after completing the actions required by paragraph (g) of this AD: Inspect the MLG left and right shock struts for nitrogen pressure, visible chrome dimension, and oil leakage, in accordance with PART E of the service bulletin. Thereafter, repeat the inspection at intervals not to exceed 500 flight cycles.

Corrective Actions for Certain Inspections

(i) If the chrome extension dimension of the shock strut pressure reading is outside the limits specified in the Airplane Maintenance Manual, Task 32–11–05–220–801, or any oil leakage is found during any inspection required by paragraph (h) of this AD: Prior to further flight, service the MLG shock strut in accordance with PART C (for airplanes on the ground) or PART D (for airplanes on jacks) of the service bulletin.

Detailed and Follow-on Inspections, and Corrective Action

(j) Prior to the accumulation of 1,000 total flight cycles on the MLG, or within 250 flight cycles after the effective date of this AD, whichever occurs later: Accomplish a detailed inspection of the MLG main fittings to detect signs of cracking (including linear paint cracks along the circumference of the main fitting tube, lack of paint (paint peeling) or other paint damage, lack of adhesion or paint bulging, and signs of corrosion), per PART A of the service bulletin. Repeat the inspection thereafter at intervals not to exceed 100 flight cycles.

Note 3: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

(k) If any linear paint crack along the circumference of the main fitting tube, lack of paint (paint peeling) or other paint damage, evidence of paint bulging due to lack of adhesion, or evidence of corrosion is found during any inspection required by paragraph (j) of this AD: Prior to further flight, accomplish either an eddy current inspection to detect cracking, per PART B of the service bulletin; or a fluorescent penetrant inspection to detect cracking, per PART F of the service bulletin.

(1) If no cracking of the MLG main fittings is found during any inspection required by paragraph (k) of this AD: Prior to further flight, repaint and/or repair/rework any paint damage per PART B of the service bulletin.

(2) If any cracking of the MLG main fittings is found during any inspection required by paragraph (k) of this AD: Prior to further flight, replace any cracked MLG main fitting with a new or serviceable part per the service bulletin.

Reporting Requirement

(l) Within 30 days after each inspection and servicing required by paragraphs (c), (d), (g), (h), (j), and (k) of this AD, report all findings, positive or negative, to: Bombardier Aerospace, In-Service Engineering, fax number 514–855–8501. Although the service bulletin references completion of a ''Service Bulletin Comment Sheet-Facsimile Reply Sheet,'' this AD does not require that action. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

Alternative Methods of Compliance

(m)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

(2) Alternative methods of compliance issued to allow escalation of the repetitive intervals for the eddy current inspections from 500 to 1,000 flight cycles, per paragraph (e) of AD 2001–22–09, are not approved as alternative methods of compliance with this AD.

Note 4: Information concerning the existence of approved alternative methods of

compliance with this AD, if any, may be obtained from the New York ACO.

Special Flight Permits

(n) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(o) Unless otherwise specified by this AD, the actions shall be done per Bombardier Alert Service Bulletin A601R–32–079, Revision ''E,'' dated September 12, 2002; including Appendix 1, Revision D, dated September 12, 2002; including Appendices 2 and 3, dated September 12, 2002; which includes the following effective pages:

Page Number	Revision Level Shown on Page	Date Shown on Page
1–30	E	September 12, 2002.
Appendix 1		
A1–A10	D	September 12, 2002.
Appendix 2		
A1–A2	Original	September 12, 2002.
Appendix 3		
A1–A8	Original	September 12, 2002.

This incorporation by reference is approved by the Director of the Federal Register, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 5: The subject of this AD is addressed in Canadian airworthiness directive CF–1999–32R2, dated September 19, 2002.

Effective Date

(p) This amendment becomes effective on June 13, 2003.

Issued in Renton, Washington, on May 20, 2003.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13120 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–285–AD; Amendment 39–13165; AD 2003–11–06]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Model ATP Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all BAE Systems (Operations) Limited Model ATP airplanes, that requires a one-time inspection of the fuel pipes within the fuel ''float switch'' test pipelines in the left and right inner wings for evidence of damage, cracks, misalignment, or fuel leakage; follow-on corrective actions, if necessary; and repetitive replacement of the fuel pipes at regular intervals. This action is necessary to prevent fuel vapors from collecting in the dry bay of the wing torsion box and consequent risk of an explosion due to fuel leakage. This action is intended to address the identified unsafe condition.

DATES: Effective July 3, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the *Office of the Federal Register,* 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all BAE Systems (Operations) Limited Model ATP airplanes was published in the **Federal Register** on February 27, 2003 (68 FR 9032). That action proposed to require a one-time inspection of the fuel pipes within the fuel ''float switch'' test pipelines in the left and right inner wings for evidence of damage, cracks, misalignment, or fuel leakage; follow-on corrective actions, if necessary; and repetitive replacement of the fuel pipes at regular intervals.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposed AD.

Conclusion

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the proposed AD regarding that material.

Cost Impact

The FAA estimates that 3 airplanes of U.S. registry will be affected by this AD.

It will take approximately 6 work hours per airplane to accomplish the

inspection, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the inspection on U.S. operators is estimated to be $1,080, or $360 per airplane.

It will take approximately 1 work hour per airplane to accomplish the records check, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the records check on U.S. operators is estimated to be $180, or $60 per airplane.

It will take approximately 5 work hours per airplane to accomplish the replacement, at an average labor rate of $60 per work hour. Required parts will be provided by the manufacturer at no cost to the operators. Based on these figures, the cost impact of the replacement on U.S. operators is estimated to be $900, or $300 per airplane, per replacement cycle.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2003–11–06 BAE Systems (Operations) Limited (Formerly British Aerospace Regional Aircraft): Amendment 39–13165. Docket 2001–NM–285–AD.

Applicability: All Model ATP airplanes, certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent fuel vapors from collecting in the dry bay of the wing torsion box and consequent risk of an explosion due to fuel leakage, accomplish the following:

Inspection and Records Check

(a) Within 90 days after the effective date of this AD, do the actions specified in paragraphs (a)(1) and (a)(2) of this AD.

(1) Do a general visual inspection of the fuel pipes within the fuel ''float switch'' test pipelines in the left and right inner wings for evidence of damage, cracks, misalignment, or fuel leakage; per BAE Systems (Operations) Limited Service Bulletin ATP–28–019, dated March 16, 2001.

Note 2: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(2) Perform a check of the airplane records to determine the actual time on the fuel pipes within the ''float switch'' test pipelines, per BAE Systems (Operations) Limited Service Bulletin ATP–28–020, dated January 25, 2002. This records check may be performed either by the cockpit flight crew or by certificated maintenance personnel.

Repetitive Replacement

(b) If no damage, crack, misalignment, or fuel leakage is found during the inspection required by paragraph (a)(1) of this AD, prior to further flight, reinstall the fuel pipes within the ''float switch'' test pipelines per BAE Systems (Operations) Limited Service Bulletin ATP–28–020, dated January 25, 2002. Thereafter, replace those pipes with new pipes at the applicable times specified in paragraph (b)(1) or (b)(2) of this AD per the service bulletin.

(1) For fuel pipes that, as of the effective date of this AD, have accumulated less than 10,000 total flight hours or 12,000 total landings since the date of installation on the airplane: Do the replacement prior to the accumulation of 10,000 total flight hours or 12,000 total landings on the pipes since the date of installation, or within 10 months after the effective date of this AD, whichever occurs latest. Thereafter, replace the fuel pipes with new pipes at intervals not to exceed 10,000 total flight hours or 12,000 total landings on the pipes, whichever occurs first. Replacement of the fuel pipes with serviceable pipes instead of new pipes is acceptable for compliance with the requirements of this paragraph, provided that: The total number of flight hours or total number of landings on those pipes can be verified, they have not accumulated 10,000 or more total flight hours or 12,000 or more total landings at the time of installation, and they are replaced prior to the accumulation of 10,000 total flight hours or 12,000 total landings (on the pipes).

(2) For fuel pipes that, as of the effective date of this AD, have accumulated 10,000 or more total flight hours or 12,000 or more total landings since the date of installation on the airplane: Do the replacement within 10 months after the effective date of this AD. Thereafter, replace the fuel pipes at intervals not to exceed 10,000 total flight hours or 12,000 total landings on the pipes, whichever occurs first. Replacement of the fuel pipes with serviceable pipes instead of new pipes is acceptable for compliance with the requirements of this paragraph, provided that: The total number of flight hours or total number of landings on those pipes can be verified, they have not accumulated 10,000 or more total flight hours or 12,000 or more total landings at the time of installation, and they are replaced prior to the accumulation of 10,000 total flight hours or 12,000 total landings (on the pipes).

(c) If any damage, crack, misalignment, or fuel leakage is found during the inspection

required by paragraph (a)(1) of this AD, prior to further flight, replace the fuel pipes with new pipes, per BAE Systems (Operations) Limited Service Bulletin ATP–28–020, dated January 25, 2002. Before or upon the accumulation of 10,000 total flight hours or 12,000 total landings on the pipes, whichever occurs first, after the replacement required by this paragraph, replace the fuel pipes with new pipes. Thereafter, replace the fuel pipes at intervals not to exceed the accumulation of 10,000 total flight hours or 12,000 total landings on the pipes, whichever occurs first. Replacement of the fuel pipes with serviceable pipes instead of new pipes is acceptable for compliance with the requirements of this paragraph, provided that: The total number of flight hours or total number of landings on those pipes can be verified, they have not accumulated 10,000 or more total flight hours or 12,000 or more total landings at the time of installation, and they are replaced prior to the accumulation of 10,000 total flight hours or 12,000 total landings (on the pipes).

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

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

Incorporation by Reference

(f) The actions must be done in accordance with BAE Systems (Operations) Limited Service Bulletin ATP–28–019, dated March 16, 2001; and BAE Systems (Operations) Limited Service Bulletin ATP–28–020, dated January 25, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the *Office of the Federal Register,* 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in British airworthiness directives 003–03–2001 and 008–01–2002.

Effective Date

(g) This amendment becomes effective on July 3, 2003.

Issued in Renton, Washington, on May 20, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13119 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–28–AD; Amendment 39–13160; AD 2003–11–01]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to all Boeing Model 747 series airplanes, that currently requires periodic inspections and cleaning of the drainage system cavity of the canted pressure deck, aft of the wing center section. This amendment adds new repetitive tests and inspections for discrepancies of the drainage system of the canted pressure deck; and corrective actions, if necessary. This amendment also terminates the requirements of the existing AD. The actions specified by this AD are intended to prevent ice accumulation on the lateral flight control cables and/or components due to water entering the wheel well of the landing gear and freezing, which could restrict or jam control cable movement, resulting in loss of controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective July 3, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Rick Kawaguchi, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6434; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 89–12–07, amendment 39–6232 (54 FR 24161, June 6, 1989), which is applicable to all Boeing Model 747 series airplanes, was published in the **Federal Register** on October 16, 2002 (67 FR 63856). The action proposed to continue to require periodic inspections and cleaning of the drainage system cavity of the canted pressure deck, aft of the wing center section. The new action proposed to add new repetitive tests and inspections for discrepancies of the drainage system of the canted pressure deck located in the wheel wells of the main landing gear of the left and right wings; and corrective actions, if necessary. The new action also proposed to terminate the requirements of the existing AD.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request To Change Compliance Times

One commenter (the manufacturer) asks that the compliance times specified in paragraphs (b), (c), and (d) of the proposed AD be changed to allow a grace period for operators of new airplanes. The commenter states that the drain system is already open and clean when the airplane is delivered.

The FAA agrees with the commenter that the drain system should already be open and clean when the airplane is delivered. Therefore, paragraphs (b), (d), and (e) of this final rule (paragraphs (b), (c), and (d) of the proposed AD) have been changed to allow a grace period relative to the date of issuance of the original airworthiness certificate, or the date of issuance of the export certificate of airworthiness, whichever is first.

Request To Clarify Summary Section

The same commenter asks that the Summary section in the proposed AD be changed, for clarification, to limit the location specified to ''the drainage system of the canted pressure deck'' to allow operators some leeway when doing the maintenance tasks. The commenter states that the intent of the proposed AD is to keep the drain system open and clean, and the phrase ''drainage system of the canted pressure deck'' refers to a series of drains normally mounted to the canted

pressure deck. The commenter adds that the drain system includes different drains and drain lines, and the drain lines are mounted in the wheel well area and the area above the fairings below the wing. The commenter notes that the phrase ''wing landing gear wheel well'' is used interchangeably with the phrase ''wheel well of the main landing gear'' throughout the proposed AD.

We agree with the commenter, and we have changed the applicable sections in this final rule for clarification to the phrase ''wheel well of the landing gear.''

The same commenter asks that the unsafe condition in the Summary section be changed to ''The actions specified by this AD are intended to prevent ice accumulation on the lateral flight control cables and/or components due to water entering the wheel well of the MLG and freezing, which could restrict or jam control cable movement, resulting in degraded or loss of controllability of the airplane.'' The commenter states that this would provide a better explanation of the unsafe condition.

We agree to add ''and/or components,'' but we do not agree to add the word ''degraded.'' The phrase ''loss of controllability of the airplane'' adequately describes the end-level effect on the airplane. ''Degraded controllability'' would not necessarily result in loss of control of the airplane, unless there were other contributing factors. We do not list all possible conditions that could result from ice accumulation—only the end-level effect.

Request To Clarify Certain Sections in the Preamble

The same commenter asks that the first and third paragraphs of the Explanation of Relevant Service Information section in the preamble of the proposed AD be changed to remove the phrase ''located in the wheel wells of the main landing gear of the left and right wings'' for clarification. The commenter also asks that the same phrase in the first paragraph of the Explanation of Requirements of Proposed Rule section be removed for clarification. The commenter also asks for minor editorial changes.

We acknowledge and agree with the commenter's remarks on the preamble of the proposed AD; however, the sections referred to are not restated in this final rule. Therefore, no change to the final rule is necessary in this regard.

Request To Change Paragraph (b)(1)

Two commenters ask for changes to paragraph (b)(1) of the proposed AD. One commenter states that the tests specified in paragraph (b)(1) do not allow any leeway to the airline. The commenter adds that operators may find it easier to use a vacuum or ''snake'' to do the test and notes that this paragraph should be changed to allow other methods to verify the drains are open and clean. The other commenter suggests that the drains at left buttock line (LBL) 45.75 and LBL 65.00 be used as an alternative means for determining the condition of the drainage of the canted pressure deck.

We do not agree to change paragraph (c)(1) of the final rule (paragraph (b)(1) of the proposed AD). We acknowledge that alternate inspection methods can be used to ensure that the drains are open and clean if such methods are submitted to the FAA for approval as an alternative method of compliance (AMOC), as provided in paragraph (g)(1) of this final rule. No change to the final rule is necessary in this regard.

Request To Change Paragraph (b)(2)

One commenter asks that the last sentence in paragraph (b)(2) of the proposed AD be changed to state, ''Accomplishment of paragraphs (b)(1) and (b)(2) of this AD replaces the requirements in paragraph (a) of this AD.'' The commenter states that the sentence is not accurate as written because doing the procedures specified in Work Package 2 does not verify that the drains are open and clean. The commenter adds that paragraph (b)(2) does not terminate the requirements in paragraph (a) of the proposed AD; it merely replaces them with new requirements.

We do not agree with the commenter. The inspection procedures required by paragraph (c)(2) of the final rule (paragraph (b)(2) of the proposed AD) meet the requirements specified in paragraph (a) of the final rule, which is to verify that all drains are open and clean. We acknowledge that the inspections required by paragraph (c)(1) of the final rule also address inspections of the drains, but the test in that paragraph goes beyond the inspection requirements in paragraph (a) of this final rule. No change to the final rule is necessary in this regard.

Request To Withdraw Proposed AD

Three commenters state that, since the issuance of AD 89–12–07, they have had no findings of drainage problems in the canted pressure deck area on the subject airplanes. The comments are as follows:

- One commenter states that it has incorporated numerous service bulletin modifications to improve the drainage of the subject area. The commenter adds that it would be interesting to determine if such modifications have been incorporated on the airplanes specified in the proposed AD and if the inspections and cleaning required by AD 89–12–07 have been done, as the commenter has done. The commenter also notes that the proposed AD is not necessary for Model 747–400 series airplanes because all the improvement modifications were incorporated per the service bulletins.
- One commenter states that the actions required by the proposed AD are done per AD 89–12–07, and per the current maintenance review board (MRB) inspections.
- One commenter provides data showing its inspection results and states that, as the data indicate, it has found virtually no trapped water in the canted pressure deck, and based on this, the actions required by the proposed AD are not necessary.

We infer that the commenters are asking that the proposed AD be withdrawn, and we do not agree. We have received several reports on Model 747–400 series airplanes, and other airplanes on which the service bulletin modifications have been incorporated to improve the drainage of the subject area, and water is still entering the landing gear wheel well and freezing. Operators of these airplanes have been inspecting the subject area per the requirements in AD 89–12–07. In addition, because the procedures specified in MRBs vary from operator to operator, there are no assurances that each operator's MRB contains the equivalent actions required by this AD. We have determined that the inspections specified in the existing MRB and AD 89–12–07 do not provide an adequate level of safety; therefore, we have determined that this final rule is appropriate and warranted. No change is made to the final rule in this regard.

Request To Extend Repetitive Test Intervals

One commenter asks that the repetitive interval for the cabin pressurization tests required by paragraph (d) of the proposed AD be extended to every 8 years so the tests can be at the ''D'' check interval because some operators have been using this interval for several years. The commenter states that the intervals specified in the proposed AD are taken from the referenced service information, and seem to be based on the MRB intervals and the present average intervals used by 747 operators. The commenter adds that the proposed AD should provide technically possible maximum intervals with substantiation. The commenter notes that the referenced service information and the

proposed AD do not make any distinction between the oldest, least modified Model 747–100 airplane, and the latest Model 747–400 airplane. The commenter states that it would be reasonable to take the airplane type and modification status into account when determining the test intervals.

We do not agree with the commenter that operators are entitled to inspection intervals based on the maximum intervals between maintenance checks, nor do we agree that the intervals should be adjusted based on the level of modification. As stated under ''Request To Withdraw Proposed AD,'' we have received reports of freezing problems found on Model 747–400 series airplanes and modified airplanes, as well as airplanes not yet modified. If operators can provide substantiating data for adjustment of the repetitive test intervals required by paragraph (e) of the final rule (paragraph (d) of the proposed AD), we will consider approving the commenter's request as an AMOC, as provided in paragraph (g)(1) of this final rule.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 1,127 airplanes of the affected design in the worldwide fleet. The FAA estimates that 255 airplanes of U.S. registry will be affected by this AD.

It takes approximately 1 work hour per airplane to accomplish the actions that are required by AD 89–12–07, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions is estimated to be $60 per airplane, per inspection cycle.

It will take approximately 12 work hours per airplane to accomplish the test/inspection/cleaning of the drainage system specified in Work Packages 1 and 2 of Boeing Alert Service Bulletin 747–51A2057, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the test/inspection/cleaning required by this AD on U.S. operators is estimated to be $183,600, or $720 per airplane, per cycle.

It will take approximately 4 work hours per airplane to accomplish the inspection specified in Work Package 3 of the service bulletin, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the inspection required by this AD on U.S. operators is estimated to be $61,200, or $240 per airplane, per inspection cycle.

It will take approximately 4 work hours per airplane to accomplish the cabin pressurization test specified in Work Package 4 of the service bulletin, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the test required by this AD on U.S. operators is estimated to be $61,200, or $240 per airplane, per test cycle.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by removing amendment 39–6232 (54 FR 24161, June 6, 1989), and by adding a new airworthiness directive (AD), amendment 39–13160, to read as follows:

2003–11–01 Boeing: Amendment 39–13160. Docket 2002–NM–28–AD. Supersedes AD 89–12–07, Amendment 39–6232.

Applicability: All Model 747 series airplanes, certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent ice accumulation on the lateral flight control cables and/or components due to water entering the wheel well of the landing gear and freezing, which could restrict or jam control cable movement, resulting in loss of controllability of the airplane, accomplish the following:

Restatement of Requirements of AD 89–12–07

Repetitive Inspections/Cleaning

(a) Within 15 months after July 10, 1989 (the effective date of AD 89–12–07, amendment 39–6232), unless accomplished 3 months before July 10, 1989, and thereafter at intervals not to exceed 18 months: Gain access to the cavity aft of the wing center section and remove all debris and foreign material, clean the cavity, and verify all drains are open and clean.

New Requirements of This AD

Repetitive Tests/Inspections of the Drainage System/Corrective Action

(b) At the later of the times specified in paragraphs (b)(1) and (b)(2) of this AD, do the actions required by paragraph (c) of this AD.

(1) Within 18 months after the effective date of this AD.

(2) Within 18 months since date of issuance of the original airworthiness certificate, or since date of issuance of the export certificate of airworthiness, whichever is first.

(c) Do the actions specified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD per the Work Instructions of Boeing Alert Service Bulletin 747–51A2057, dated February 21, 2002.

(1) Do a test (including doing a general visual inspection of the external drains, reducer, and drain lines, and sending 3 to 5 pounds per square inch compressed air through the drain line) of the drainage system of the canted pressure deck for discrepancies (including damage, holes, signs of frozen water, and signs of blockage), per Work Package 1 of the Work Instructions of the service bulletin. Repeat the test at least every 18 months.

(2) Clean the drainage system for the canted pressure deck, and do a general visual inspection of the system for discrepancies, per Work Package 2 of the Work Instructions of the service bulletin. Repeat the cleaning and inspection at least every 18 months. Accomplishment of this paragraph terminates the requirements in paragraph (a) of this AD.

(3) Except as required by paragraph (f) of this AD: If any discrepancy is found during any inspection or test required by paragraphs (c)(1) and (c)(2) of this AD, before further flight, repair per the Work Instructions of the service bulletin.

Repetitive Inspections of the Canted Pressure Deck/Corrective Action

(d) At the later of the times specified in paragraphs (d)(1) and (d)(2) of this AD: Do a general visual inspection of the canted pressure deck for discrepancies (including loose or missing fasteners; loose, missing, or cracked sealant; and leak paths), per Work Package 3 of the Work Instructions of Boeing Alert Service Bulletin 747–51A2057, dated February 21, 2002. If any discrepancy is found, before further flight, repair (including replacing any loose or missing fastener or loose, missing, or cracked sealant; and repairing any leak found) per the service bulletin; except as required by paragraph (f) of this AD. Repeat the inspection at least every 36 months.

Note 2: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(1) Within 36 months after the effective date of this AD.

(2) Within 36 months since date of issuance of the original airworthiness certificate, or since date of issuance of the export certificate of airworthiness, whichever is first.

Repetitive Cabin Pressurization Tests/ Corrective Action

(e) At the later of the times specified in paragraphs (e)(1) and (e)(2) of this AD: Do a cabin pressurization test to check for leaks in the canted pressure deck, per Work Package 4 of the Work Instructions of Boeing Alert Service Bulletin 747–51A2057, dated February 21, 2002. If any leak is found, before further flight, repair per the service bulletin; except as required by paragraph (f) of this AD. Repeat the cabin pressurization test at least every 72 months.

(1) Within 72 months after the effective date of this AD.

(2) Within 72 months since date of issuance of the original airworthiness certificate, or since date of issuance of the export certificate of airworthiness, whichever is first.

Corrective Action per Seattle Aircraft Certification Office (ACO)

(f) If any discrepancy is found during any inspection or test required by this AD and the service bulletin specifies to contact Boeing for appropriate action: Before further flight, repair per a method approved by the Manager, Seattle ACO, FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

Alternative Methods of Compliance

(g)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

(2) Alternative methods of compliance, approved previously in accordance with AD 89–12–07, amendment 39–6232, are approved as alternative methods of compliance with paragraph (c)(2) of this AD.

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

Special Flight Permits

(h) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(i) Unless otherwise provided in this AD, the actions shall be done in accordance with Boeing Alert Service Bulletin 747–51A2057, dated February 21, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(j) This amendment becomes effective on July 3, 2003.

Issued in Renton, Washington, on May 20, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13118 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–19–AD; Amendment 39–13162; AD 2003–11–03]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727, 737–100, 737–200, and 737–200C Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 727, 737–100, 737–200, and 737–200C series airplanes, that requires one-time inspections to determine the part numbers of hydraulic accumulators installed in various areas of the airplane, and follow-on corrective actions if necessary. The actions specified by this AD are intended to prevent high-velocity separation of a barrel, piston, or end cap from a hydraulic accumulator. Such separation could result in injury to personnel in the accumulator area; loss of cabin pressurization; loss of affected hydraulic systems; or damage to plumbing, electrical installations, or structural members. This action is intended to address the identified unsafe condition.

DATES: Effective July 3, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle,

Washington 98124–2207. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Barbara Mudrovich, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6477; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Boeing Model 727, 737–100, 737–200, and 737–200C series airplanes was published as a supplemental notice of proposed rulemaking (NPRM) in the **Federal Register** on January 3, 2003 (68 FR 311). That supplemental NPRM proposed to require one-time inspections to determine the part numbers of hydraulic accumulators installed in various areas of the airplane, and follow-on corrective actions if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received.

Request To Remove a Certain Part Number

The commenter, the manufacturer, asks that Boeing part number (P/N) BACA11E4S (vendor P/N 60857–4) be removed from paragraphs (b)(3) and (c)(3) of the proposed AD. The commenter states that the proposed AD specifies replacement of the existing clamps and mounting hardware with stronger clamps and hardware if a hydraulic accumulator having P/N BACA11E4S is installed. The commenter adds that Boeing P/N BACA11E4S is an acceptable alternative to the suspect accumulators and was identified in the service bulletins referenced in those paragraphs as needing no work if installed. The commenter concludes that it is not necessary to replace existing accumulator clamps and mounting hardware for these accumulators, as the existing clamps and mounting hardware have been analyzed and found to be sufficient for the anticipated loads.

The FAA agrees with the commenter. The referenced service bulletins specify that no action is required if the subject part number is installed. Hydraulic accumulators having vendor P/N 60857–4 are equivalent to P/N BACA11E4S; these accumulators have aluminum end caps but are an acceptable alternative to the discrepant accumulators. We have removed P/N BACA11E4S from paragraphs (b)(3) and (c)(3) of this final rule.

Conclusion

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 1,832 Model 727 series airplanes and 1,033 Model 737 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,294 Model 727 series airplanes and 376 Model 737 series airplanes of U.S. registry will be affected by this AD.

We estimate that it will take approximately 1 work hour per airplane to accomplish each one-time inspection, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of each one-time inspection on U.S. operators is estimated to be $100, $200, or $60 per airplane.

Cost Impact: On-Condition Actions

For an airplane subject to the replacement per Service Bulletin 727–29–0064, we estimate that it will take approximately 5 work hours per accumulator (two hydraulic system accumulators per airplane) to accomplish, at an average labor rate of $60 per work hour. Required parts will cost between $1,400 (new part) and $2,810 (vendor-modified part) per accumulator. Based on these figures, the cost impact of this replacement, if necessary, will be between $1,700 and $3,110 per accumulator.

For an airplane subject to the replacement of both the mounting clamps and hardware and the hydraulic accumulator per Service Bulletin 727–32–0410, we estimate that it will take approximately 6 work hours per airplane to accomplish (one landing gear brake accumulator per airplane), at an average labor rate of $60 per work hour. Required parts will cost between $2,500 (new part) and $3,975 (vendor-modified part) per airplane. Based on these figures, the cost impact of this replacement, if necessary, will be between $2,860 and $4,335 per airplane.

For an airplane subject to the replacement of both the mounting clamps and hardware and the hydraulic accumulator per Service Bulletin 727–52–0148, we estimate that it will take approximately 6 work hours per airplane to accomplish (one aft airstairs hydraulic accumulator per airplane), at an average labor rate of $60 per work hour. Required parts will cost between $2,500 (new part) and $3,975 (vendor-modified part) per airplane. Based on these figures, the cost impact of this replacement, if necessary, will be between $2,860 and $4,335 per airplane.

For an airplane subject to the replacement per Service Bulletin 737–32–1334, we estimate that it will take approximately 5 work hours per accumulator to accomplish (two landing gear hydraulic brake accumulators per airplane), at an average labor rate of $60 per work hour. Required parts will cost between $2,175 (operator-modified part) and $2,410 (vendor-modified part) per accumulator. Based on these figures, the cost impact of this replacement, if necessary, will be between $2,475 and $2,710 per accumulator.

For an airplane subject to the replacement per Service Bulletin 737–78–1068, we estimate that it will take approximately 5 work hours per accumulator to accomplish, at an average labor rate of $60 per work hour. Required parts will cost between $2,175 (operator-modified part) and $2,410 (vendor-modified part) per accumulator. Based on these figures, the cost impact of this replacement, if necessary, will be between $2,475 and $2,710 per accumulator.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is

determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2003–11–03 Boeing: Amendment 39–13162. Docket 2002–NM–19–AD.

Applicability: Model 727 series airplanes, line numbers (L/N) 1 through 1832 inclusive; and Model 737–100, –200, and –200C series airplanes, L/N 1 through 1033 inclusive; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent high-velocity separation of a barrel, piston, or end cap from a hydraulic accumulator, which could result in injury to personnel in the accumulator area; loss of cabin pressurization; loss of affected hydraulic systems; or damage to plumbing, electrical installations, or structural members; accomplish the following:

Inspection/Corrective Action: Service Bulletin 727–29–0064

(a) For airplanes listed in Boeing Special Attention Service Bulletin 727–29–0064, Revision 1, dated May 3, 2001: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, do a one-time inspection to determine the part numbers (P/Ns) of hydraulic accumulators in hydraulic systems ''A'' and ''B,'' per the Accomplishment Instructions of the service bulletin.

(1) If no hydraulic accumulator with Parker P/N 1356–603303 is installed: No further action is required by this paragraph.

(2) If any hydraulic accumulator with Parker P/N 1356–603303 is installed: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, replace the subject hydraulic accumulator with a new or modified accumulator, per the service bulletin.

Note 2: Boeing Special Attention Service Bulletin 727–29–0064, Revision 1, refers to Parker Service Bulletin 1356–603303–29–60, dated January 9, 2001, as the appropriate source of service information for modification of the hydraulic accumulators that are subject to replacement per Service Bulletin 727–29–0064, Revision 1.

Inspection/Corrective Action: Service Bulletin 727–32–0410

(b) For airplanes listed in Boeing Special Attention Service Bulletin 727–32–0410, Revision 2, dated January 24, 2002: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, do a one-time inspection to determine the P/N of the hydraulic accumulator in the landing gear brake system, per the service bulletin.

(1) If no hydraulic accumulator with P/N 1356–603399, 3780078–104, BACA11E4S, BACA11E4SA, 60857–4–1, or BACA11E4 (vendor P/N 2660472–4 or 2660472M4) is installed: No further action is required by this paragraph.

(2) If any hydraulic accumulator with P/N 1356–603399 or BACA11E4 (vendor P/N 2660472–4 or 2660472M4) is installed: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, replace existing accumulator clamps and mounting hardware with new, stronger accumulator clamps and mounting hardware, and replace the subject hydraulic accumulator with a new or modified accumulator, per the service bulletin.

(3) If any hydraulic accumulator with P/N 3780078–104, BACA11E4SA, or 60857–4–1 is installed: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, replace existing accumulator clamps and mounting hardware with new, stronger accumulator clamps and mounting hardware, per the service bulletin.

Note 3: Boeing Special Attention Service Bulletin 727–32–0410, Revision 2, refers to Parker Service Bulletins 1356–603399–29–61 and 2660472–29–63, both dated December 12, 2000, as the appropriate sources of service information for modification of the hydraulic accumulators that are subject to replacement per Service Bulletin 727–32–0410, Revision 2.

Inspection/Corrective Action: Service Bulletin 727–52–0148

(c) For airplanes listed in Boeing Special Attention Service Bulletin 727–52–0148, Revision 2, dated January 24, 2002: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, do a one-time inspection to determine the P/N of the hydraulic accumulator in the aft airstairs, per the service bulletin.

(1) If no hydraulic accumulator with P/N 1356–603399, 3780078–104, BACA11E4S, BACA11E4SA, 60857–4–1, or BACA11E4 (vendor P/N 2660472–4 or 2660472M4) is installed: No further action is required by this paragraph.

(2) If any hydraulic accumulator with P/N 1356–603399 or BACA11E4 (vendor P/N 2660472–4 or 2660472M4) is installed: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, replace existing accumulator clamps and mounting hardware with new, stronger accumulator clamps and mounting hardware, and replace the subject hydraulic accumulator with a new or modified accumulator, per the service bulletin.

(3) If any hydraulic accumulator with P/N 3780078–104, BACA11E4SA, or 60857–4–1 is installed: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, replace existing accumulator clamps and mounting hardware with new, stronger accumulator clamps and mounting hardware, per the service bulletin.

Note 4: Boeing Special Attention Service Bulletin 727–52–0148, Revision 2, refers to Parker Service Bulletins 1356–603399–29–61 and 2660472–29–63, both dated December 12, 2000, as the appropriate sources of service information for modification of the hydraulic accumulators that are subject to replacement per Service Bulletin 727–52–0148, Revision 2.

Inspection/Corrective Action: Service Bulletin 737–32–1334

(d) For airplanes listed in Boeing Special Attention Service Bulletin 737–32–1334, Revision 1, dated March 1, 2001: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, do a one-time inspection to determine the P/Ns of the hydraulic accumulators in the landing gear brake system, per the service bulletin.

(1) If no hydraulic accumulator with P/N BACA11E2 (vendor P/N 2660472–2 or 2660472M2) is installed: No further action is required by this paragraph.

(2) If any hydraulic accumulator with P/N BACA11E2 (vendor P/N 2660472–2 or 2660472M2) is installed: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, replace the subject hydraulic accumulator with a new or

modified accumulator, per the service bulletin.

Note 5: Boeing Special Attention Service Bulletin 737–32–1334, Revision 1, refers to Parker Service Bulletin 2660472–29–63, dated December 12, 2000, as the appropriate source of service information for modification of the hydraulic accumulators that are subject to replacement per Service Bulletin 737–32–1334, Revision 1.

Inspection/Corrective Action: Service Bulletin 737–78–1068

(e) For airplanes listed in Boeing Special Attention Service Bulletin 737–78–1068, Revision 1, dated March 1, 2001: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, do a one-time inspection to determine the P/Ns of the hydraulic accumulators in the thrust reverser actuation system, per the service bulletin.

(1) If no hydraulic accumulator with P/N BACA11E2 (vendor P/N 2660472–2 or 2660472M2) is installed: No further action is required by this paragraph.

(2) If any hydraulic accumulator with P/N BACA11E2 (vendor P/N 2660472–2 or 2660472M2) is installed: Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is first, replace the subject hydraulic accumulator with a new or modified accumulator, per the service bulletin.

Note 6: Boeing Special Attention Service Bulletin 737–78–1068, Revision 1, refers to Parker Service Bulletin 2660472–29–63, dated December 12, 2000, as the appropriate source of service information for modification of the hydraulic accumulators that are subject to replacement per Service Bulletin 737–78–1068, Revision 1.

Inspections Accomplished per Previous Issues of Service Bulletins

(f) Inspections and replacements accomplished before the effective date of this AD per Boeing Special Attention Service Bulletin 727–29–0064, dated June 8, 2000, are considered acceptable for compliance with the corresponding action required by paragraph (a) of this AD.

(g) Inspections and replacements accomplished before the effective date of this AD per Boeing Special Attention Service Bulletin 737–32–1334, dated May 11, 2000, are considered acceptable for compliance with the corresponding actions required by paragraph (d) of this AD.

(h) Inspections and replacements accomplished before the effective date of this AD per Boeing Special Attention Service Bulletin 737–78–1068, dated June 8, 2000, are considered acceptable for compliance with the corresponding action required by paragraph (e) of this AD.

Part Installation

(i) As of the effective date of this AD, no one may install a hydraulic accumulator with a P/N listed in paragraph (a)(2), (b)(2), (c)(2), (d)(2), or (e)(2) of this AD on any airplane.

Alternative Methods of Compliance

(j) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 7: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(k) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(l) Unless provided otherwise in this AD, the actions shall be done in accordance with Boeing Special Attention Service Bulletin 727–29–0064, Revision 1, dated May 3, 2001; Boeing Special Attention Service Bulletin 727–32–0410, Revision 2, dated January 24, 2002; Boeing Special Attention Service Bulletin 727–52–0148, Revision 2, dated January 24, 2002; Boeing Special Attention Service Bulletin 737–32–1334, Revision 1, dated March 1, 2001; and Boeing Special Attention Service Bulletin 737–78–1068, Revision 1, dated March 1, 2001; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(m) This amendment becomes effective on July 3, 2003.

Issued in Renton, Washington, on May 20, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13117 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–196–AD; Amendment 39–13161; AD 2003–11–02]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–90–30 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all McDonnell Douglas Model MD–90–30 airplanes, that requires replacement of the starter relay of the auxiliary power unit (APU) with a new, improved relay. The actions specified by this AD are intended to prevent failure of the APU starter relay, which could result in depleted main airplane batteries, overheated APU starters, and damage to the wiring adjacent to the APU starter. This action is intended to address the identified unsafe condition.

DATES: Effective July 3, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: William S. Bond, Aerospace Engineer, Propulsion Branch, ANM–140L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5253; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all McDonnell Douglas Model MD–90–30 airplanes was published in the **Federal Register** on March 3, 2003 (68 FR 9950). That action proposed to require replacement of the starter relay of the auxiliary power unit (APU) with a new, improved relay.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Changes to 14 CFR Part 39/Effect on the Final Rule

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the NPRM regarding that material.

Cost Impact

There are approximately 110 airplanes of the affected design in the worldwide fleet. The FAA estimates that 21 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $1,039 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $23,079, or $1,099 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2003–11–02 McDonnell Douglas: Amendment 39–13161. Docket 2001–NM–196–AD.

Applicability: All Model MD–90–30 airplanes, certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the starter relay of the auxiliary power unit (APU), which could result in depleted main airplane batteries, overheated APU starters, and damage to the wiring adjacent to the APU starter, accomplish the following:

Starter Relay Replacement

(a) Within 6 months after the effective date of this AD, replace the APU starter relay with a new, improved relay, in accordance with McDonnell Douglas Alert Service Bulletin MD90–49A025, Revision 01, dated April 16, 2002.

(b) Replacement of the APU starter relay before the effective date of this AD, in accordance with McDonnell Douglas Alert Service Bulletin MD90–49A025, dated December 13, 2000, is acceptable for compliance with the requirements of this AD.

Parts Installation

(c) As of the effective date of this AD, no person may install a contactor (starter relay) having part number 5D0387–1, A–770–WA–3, or AH–CXA–016 on any airplane.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

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

Special Flight Permits

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

Incorporation by Reference

(f) Unless otherwise provided in this AD, the actions shall be done in accordance with McDonnell Douglas Alert Service Bulletin MD90–49A025, Revision 01, dated April 16, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1-L5A (D800–0024). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(g) This amendment becomes effective on July 3, 2003.

Issued in Renton, Washington, on May 20, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13116 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NE–12–AD; Amendment 39–13168; AD 2003–11–09]

RIN 2120–AA64

Airworthiness Directives; Turbomeca Turmo IV A and IV C Series Turboshaft Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), that is applicable to Turbomeca Turmo IV A and IV C series turboshaft engines. This amendment requires initial and repetitive borescope and eddy current or ultrasonic inspections of centrifugal compressor intake wheel blades for cracks and evidence of corrosion pitting, and, if found cracked or if there is evidence of corrosion pitting, replacement with serviceable parts. This amendment is prompted by reports of cracked centrifugal compressor intake wheel blades, resulting in the release of one or more blade fragments. The actions specified by this AD are intended to prevent centrifugal compressor intake wheel blade cracks, which can result in in-flight engine power loss or shutdown.

DATES: Effective July 3, 2003. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Turbomeca, 40220 Tarnos, France; telephone (33) 05 59 64 40 00; fax (33) 05 59 64 60 80. This information may be examined, by appointment, at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Antonio Cancelliere, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7751; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that is applicable to Turbomeca Turmo IV A and IV C series turboshaft engines was published in the **Federal Register** on December 2, 2002 (67 FR 71493). That action proposed to require initial and repetitive borescope and eddy current or ultrasonic inspections of centrifugal compressor intake wheel blades for cracks and evidence of corrosion pitting, and, if found cracked or if there is evidence of corrosion pitting, replacement with serviceable parts in accordance with Turbomeca Turmo IV service bulletin (SB) 249 72 0117, dated March 11, 2001; and Turbomeca Turmo IV SB 249 72 0100, Update 4, dated January 25, 2000.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public.

Editorial Corrections

A typographical error is being corrected in the AD relative to the issue date of Turbomeca Turmo IV SB 249 72 0117. The Notice of Proposed Rule Making (NPRM) lists the issue date as March 11, 2000. That date is corrected in the AD to March 11, 2001.

A typographical error is also being corrected in the Regulatory requirements of the AD. Paragraph (e) is corrected to (d) and paragraph (f) is corrected to (e).

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously. The FAA has determined that these changes will neither increase the ecomomic burden on any operator nor increase the scope of the AD.

Economic Analysis

There are approximately 1,110 Turbomeca Turmo IV A and IV C series turboshaft engines of the affected design in the worldwide fleet. The FAA estimates that 11 engines installed on helicopters of U.S. registry will be affected by this AD, that it will take approximately 41 work hours per engine to perform the required inspections, including disassembling and assembling engines and that the average labor rate is $60 per work hour. A replacement centrifugal compressor assembly costs approximately $21,651. Based on these figures, the total cost per inspection to U.S. operators is estimated to be $265,221.

Regulatory Analysis

This final rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this final rule.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2003–11–09 Turbomeca: Amendment 39–13168. Docket No. 99–NE–12–AD.

Applicability: This airworthiness directive (AD) is applicable to Turbomeca Turmo IV A and IV C series turboshaft engines. These engines are installed on but not limited to Aerospatiale FA 330—PUMA helicopters.

Note 1: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the

owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Compliance is required as indicated, unless already done;

To prevent centrifugal compressor intake wheel blade cracks, which can result in in-flight engine power loss or shutdown, do the following:

(a) For engines that have been modified to TU 197 standard, but have not been modified to TU 191 or TU 224 standard, do the following:

(1) Remove modification TU 197 and install modification TU 224 in accordance with Turmo IV SB 249 72 0117, dated March 11, 2001, within the next 50 cycles or six months after the effective date of the AD, whichever occurs first.

(2) Within 1,000 flight hours (FH) after the installation of modification TU 224 standard, do the following:

(i) Perform a visual inspection and an ultrasonic inspection (USI) in accordance with paragraph 2.B.(3) of Turbomeca Turmo IV SB 249 72 0100, Update 4, dated January 25, 2000.

(ii) Thereafter, perform a visual inspection and a USI at intervals not to exceed 1,000 FH in accordance with paragraph 2.B.(3) of Turbomeca Turmo IV SB 249 72 0100, Update 4, dated January 25, 2000.

(b) For engines that have not been modified to TU 191, TU 197, or TU 224 standard, do the following in accordance with Turbomeca Turmo IV SB 249 72 0100, Update 4, dated January 25, 2000:

(1) For centrifugal compressor intake wheels that, on the effective date of this AD, have been operated for more than 250 FH since the last inspection of the centrifugal compressor intake wheel blades, do the following:

(i) Perform an initial borescope inspection of the blades for evidence of corrosion within the next 50 FH, or six months after the effective date of this AD, whichever occurs first, in accordance with paragraph 2.B.(1) of the SB.

(ii) If corrosion is found, perform an eddy current inspection (ECI) or USI, as applicable, of the blades for cracks within 50 FH after the borescope inspection performed in accordance with paragraph 2.B.(3) of the SB, and if necessary, replace with serviceable parts.

(iii) If corrosion is not found, perform an ECI or USI, as applicable, of the blades for cracks within 250 FH after the borescope inspection performed in accordance with paragraph (b)(1)(i) of this AD, and if necessary, replace with serviceable parts.

(iv) Thereafter, perform borescope inspections and ECIs or USIs, as applicable, of the blades for cracks and evidence of corrosion, alternating at intervals not to exceed 250 FH since the last inspection.

(v) Remove from service centrifugal compressor intake wheels found cracked and replace with serviceable parts.

(2) For centrifugal compressor intake wheels that, upon the effective date of this AD, have been operated for less than or equal to 250 FH since the last inspection of the blades, do the following:

(i) Perform an initial borescope inspection of the blades for evidence of corrosion prior to accumulating 250 FH since the last inspection of the blades in accordance with paragraph 2.B.(1) of the SB.

(ii) If corrosion is found, perform an ECI or USI, as applicable, of the blades for cracks, and, if necessary, replace with serviceable parts, within 50 FH after the borescope inspection performed in accordance with paragraph 2.B.(3) of the SB.

(iii) If corrosion is not found, perform an ECI or USI, as applicable, of the blades for cracks, and, if necessary, replace with serviceable parts, within 250 FH after the borescope inspection performed in accordance with paragraph (b)(2)(i) of this AD.

(iv) Thereafter, perform borescope inspections and ECIs or USIs, as applicable, of the blades for cracks and evidence of corrosion, alternating at intervals not to exceed 250 FH since the last inspection.

Note 2: Alternating intervals means that if the last inspection was an ECI or a USI, the next inspection will be a borescope inspection. If the last inspection was a borescope inspection, the next 250 FH inspection will be an ECI or a USI as applicable.

(v) Remove from service centrifugal compressor intake wheels found cracked and replace with serviceable parts.

(c) For engines not modified to TU 197 but have been modified to TU 191 or TU 224 standard, that have been operated for more than 1,000 flight hours since the last inspection of the blades, do the following in accordance with Turbomeca Turmo IV SB 249 72 0100, Update 4, dated January 25, 2000:

(1) Perform an initial ECI or USI, as applicable, of the blades for cracks, in accordance with paragraph 2.B.(3) of the SB, within the next 50 FH, or 6 months after the effective date of this AD, whichever occurs first.

(2) Thereafter, inspect at intervals not to exceed 1,000 FH.

(3) Remove from service centrifugal compressor intake wheels found cracked, and replace with a serviceable part.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be done.

Documents That Have Been Incorporated by Reference

(f) The inspections must be done in accordance with the following Turbomeca service bulletins:

Document No.	Pages	Revision	Date
Turmo IV SB 249 72 0100 Total pages: 12	All	Update No. 4	January 25, 2000.
Turmo IV SB 249 72 0117 Total pages: 5	All	Original	March 11, 2001.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Turbomeca, 40220 Tarnos, France; telephone (33) 05 59 64 40 00; fax (33) 05 59 64 60 80. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in Direction Generale de L'Aviation Civile airworthiness directive AD97–122(B), dated May 21, 1997.

Effective Date

(g) This amendment becomes effective on July 3, 2003.

Issued in Burlington, Massachusetts, on May 20, 2003.

Francis A. Favara,

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

[FR Doc. 03–13115 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NE–39–AD; Amendment 39–13169; AD 2003–11–10]

RIN 2120–AA64

Airworthiness Directives; Turbomeca S.A. Arrius –2F Turboshaft Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), that is applicable to Turbomeca S.A. Arrius –2F turboshaft engines with certain serial number (SN) Fuel Control Units (FCUs). This amendment requires adjusting the FCU maximum fuel flow mechanical stop position to a higher fuel flow setting. This amendment is prompted by an FCU discovered to have a maximum fuel flow limit adjusted below the maximum required setting. The actions specified by this AD are intended to prevent reduced maximum available power during takeoff, landing, or an emergency, which could significantly affect helicopter performance and result in loss of the helicopter.

DATES: Effective July 3, 2003. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Turbomeca S.A., 64511 Bordes Cedex, France; telephone 33 05 59 64 40 00, fax 33 05 59 64 60 80. This information may be examined, by appointment, at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Antonio Cancelliere, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7751; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that is applicable to Turbomeca S.A. Arrius –2F turboshaft engines with certain SN FCUs was published in the **Federal Register** on February 5, 2003 (68 FR 5856). That action proposed to require adjusting the FCU maximum fuel flow mechanical stop position to a higher fuel flow setting in accordance with Alert Service Bulletin (ASB) No. A319 73 4808, dated September 1, 2000.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Economic Analysis

There are approximately 334 Turbomeca S.A. Arrius –2F turboshaft engines of the affected design in the worldwide fleet. The FAA estimates that four engines installed on aircraft of U.S. registry will be affected by this AD, that it will take approximately three work hours per engine to perform the required actions, and that the average labor rate is $60 per work hour. Required tooling would cost approximately $300 per engine. Based on these figures, the total cost of the AD to U.S. operators is estimated to be $1,920. The manufacturer has advised the FAA and Direction Generale de L'Aviation Civile, which is the airworthiness authority for France, that the operator may be provided with material and tooling at no cost to the operator, thereby substantially reducing the cost of the AD.

Regulatory Analysis

This final rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this final rule.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2003–11–10 Turbomeca S.A.: Amendment 39–13169. Docket No. 2002–NE–39–AD.

Applicability: This airworthiness directive (AD) is applicable to Turbomeca S.A. Arrius –2F turboshaft engines with Fuel Control Units (FCUs) part numbers (P/Ns) 0 319 92 832 0, 0 319 92 830 0, and 0 319 92 825 0, with FCU serial numbers (SNs) in the following Table 1:

TABLE 1.—AFFECTED FCU SERIAL NUMBERS

102B	135B	166B
103B	136B	167B
104B	137B	168B
105B	138B	169B
106B	139B	171B
107B	140B	173B
108B	141B	174B
110B	142B	175B
111B	143B	176B
112B	144B	177B
113B	145B	178B
114B	146B	180B
115B	148B	181B
116B	149B	182B
118B	150B	183B
120B	153B	185B
122B	155B	186B
123B	156B	190B
124B	158B	191B
126B	159B	193B
129B	161B	199B
132B	164B	N/A
133B	165B	N/A

These engines are installed on, but not limited to Eurocopter 120B ''Colibri'' helicopters.

Note 1: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area

subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Compliance with this AD is required within 120 days after the effective date of this AD, unless already done.

To prevent reduced maximum available power during takeoff, landing, or an emergency, which could significantly affect helicopter performance, and result in loss of the helicopter, do the following:

(a) For FCUs listed in the applicability of this AD, adjust the maximum fuel flow mechanical stop position to a higher fuel flow setting, in accordance with paragraphs 2.A.(1) and 2.B.(1) of Turbomeca S.A Alert Service Bulletin (ASB) No. A319 73 4808, dated September 1, 2000.

(b) Perform a ground run check and a check flight in accordance with paragraph 2.C.(1) of Turbomeca S.A ASB No. A319 73 4808, dated September 1, 2000.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be done.

Documents That Have Been Incorporated by Reference

(e) The actions must be done in accordance with Turbomeca S.A. Alert Service Bulletin No. A319 73 4808, dated September 1, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Turbomeca S.A., 64511 Bordes Cedex, France; telephone 33 05 59 64 40 00, fax 33 05 59 64 60 80. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Direction Generale de L'Aviation Civile AD 2000–482(A), dated November 29, 2000.

Effective Date

(f) This amendment becomes effective on July 3, 2003.

Issued in Burlington, Massachusetts, on May 20, 2003.

Francis A. Favara,

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

[FR Doc. 03–13114 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NE–38–AD; Amendment 39–13167; AD 2003–11–08]

RIN 2120–AA64

Airworthiness Directives; Turbomeca S.A. Arriel –1B, –1D, and –1D1 Series Turboshaft Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to Turbomeca S.A. Arriel –1B, –1D, and –1D1 series turboshaft engines. This amendment requires replacement of modules M03 modified to TU 204 standard with modules M03 not modified to TU 204 standard. This amendment is prompted by several reports of 2nd stage gas generator turbine blade failures. The actions specified by this AD are intended to prevent 2nd stage gas generator turbine blade failure resulting in uncommanded engine in-flight shutdown.

DATES: Effective July 3, 2003. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Turbomeca S.A., 64511 Bordes Cedex, France; telephone 33 05 59 64 40 00; fax 33 05 59 64 60 80. This information may be examined, by appointment, at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Antonio Cancelliere, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7751; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that is applicable to Turbomeca S.A. Arriel –1B, –1D, and –1D1 series turboshaft engines was published in the **Federal Register** on February 7, 2003 (68 FR 6380). That action proposed to require replacement of modules M03 modified to TU 204 standard with modules M03 not modified to TU 204 standard in accordance with Turbomeca S.A. Service Bulletin (SB) No. 292 72 0258, Update No. 1, dated April 4, 2002, and SB No. 292 72 0265, Update No. 1, dated August 18, 2000.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request To Expand Applicability

One commenter requests that the applicability be expanded to include Turbomeca engine model –1S1. The –1S1 engine model powers the twin-engine S76 helicopter, and the commenter states that the –1S1 engine model is the same type design as the –1B, –1D, and –1D1 model series turboshaft engines. The commenter states that the –1S1 engine model can incorporate the same high pressure turbine (HPT) blade modification TU 204, and is, therefore, affected by the same risk failure as the other engine models.

The FAA does not agree. The FAA recognizes that the –1S1 engine model may have the same probability of failure as the other engine models installed on the single engine helicopter application if the HPT blade modification TU 204 is installed. However, the probability of a dual-engine failure on a twin-engine helicopter, and the risk of loss of the helicopter, is very low. Furthermore, the engine manufacturer issued instructions (Turbomeca S.A. mandatory SB No. 292 72 0288, dated October 21, 2002) to retire the HPT blades with modification TU 204 installed on the –1S1 engine model. The FAA believes that no specific action is necessary at this time for the –1S1 engine model to increase safety on the twin-engine helicopter application. Therefore, the applicability in this AD is not changed.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Economic Analysis

There are approximately 1,319 Turbomeca S.A. Arriel –1B, –1D, and –1D1 series turboshaft engines of the affected design in the worldwide fleet. The FAA estimates that 48 engines installed on helicopters of U.S. registry will be affected by this AD, that it will take approximately 12 work hours per engine to perform the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $160,000 per engine. Based on these figures, the total cost of the AD to U.S. operators is estimated to be $7,714,560. Turbomeca has advised the FAA that material and tooling may be provided at no cost to the operator, thereby substantially reducing the cost of the final rule.

Regulatory Analysis

This final rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this final rule.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2003–11–08 Turbomeca S.A.: Amendment 39–13167. Docket No. 2002–NE–38–AD.

Applicability: This airworthiness directive (AD) is applicable to Turbomeca S.A. Arriel –1B, –1D, and –1D1 series turboshaft engines. These engines are installed on, but not limited to Eurocopter AS–350B ''Astar'' helicopters.

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

Compliance: Compliance with this AD is required at the next engine shop visit, but no later than August 31, 2003, unless already done.

To prevent 2nd stage gas generator turbine blade failure resulting in uncommanded engine in-flight shutdown, do the following:

(a) For Arriel –1B engines, replace TU 204 Standard modules M03 with modules M03 not modified to TU 204 standard, in accordance with Paragraphs 2.A. through 2.C. of Turbomeca S.A. Service Bulletin (SB) No. 292 72 0258, Update No. 1, dated April 4, 2002.

(b) For Arriel –1D and –1D1 engines, replace TU 204 Standard modules M03 with modules M03 not modified to TU 204 standard, in accordance with Paragraphs 2.A. through 2.C. of Turbomeca S.A. SB No. 292 72 0265, Update No. 1, dated August 18, 2000.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be done.

Documents That Have Been Incorporated by Reference

(e) The actions must be done in accordance with the following Turbomeca S.A. service bulletins (SBs):

Document No.	Pages	Revision	Date
SB No. 292 72 0258 ..... Total pages: 8	All	Update No. 1	April 4, 2002.
SB No. 292 72 0265 ..... Total pages: 6	All	Update No. 1	August 18, 2000.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Turbomeca S.A., 64511 Bordes Cedex, France; telephone 33 05 59 64 40 00; fax 33 05 59 64 60 80. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Direction Generale de L'Aviation Civile airworthiness directive 2002–258(A), dated May 15, 2002.

Effective Date

(f) This amendment becomes effective on July 3, 2003.

Issued in Burlington, Massachusetts, on May 16, 2003.

Francis A. Favara,

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

[FR Doc. 03–13113 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–358–AD; Amendment 39–13163; AD 2003–11–04]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F, DC–10–30F (KC–10A and KDC–10), DC–10–40, and DC–10–40F Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain McDonnell Douglas airplanes, that requires inspections of the linear variable differential transducers (LVDTs) of the autopilot for discrepancies, and follow-on actions if necessary. This amendment is prompted by information from the manufacturer advising that certain LVDTs were delivered with an undersize nylok element on the threaded extension. The actions specified by this AD are intended to prevent failure of the LVDTs, which could result in an automatic pitch trim malfunction or an autopilot disconnect, and consequent reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective July 3, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 3, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ron Atmur, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5224; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F, DC–10–30F (KC–10A and KDC–10), DC–10–40, and DC–10–40F airplanes was published as a supplemental notice of proposed rulemaking (NPRM) in the **Federal Register** on March 17, 2003 (68 FR 12618). That action proposed to require inspections of the linear variable differential transducers (LVDTs) of the autopilot for discrepancies, and follow-on actions if necessary. That action also proposed to expand the applicability of the original NPRM.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed in the supplmental NPRM.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. However, for clarity and consistency in this final rule, we have retained the language of the supplemental NPRM regarding that material.

Cost Impact

There are approximately 394 Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F, DC–10–30F (KC–10A and KDC–10), DC–10–40, and DC–10–40F airplanes of the affected design in the worldwide fleet. The FAA estimates that 252 airplanes of U.S. registry will be affected by this AD.

We estimate that it will take approximately 1 work hour per airplane to accomplish the inspection specified in Boeing Alert Service Bulletin DC10–22A126, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of that inspection required by this AD on U.S. operators is estimated to be $15,120, or $60 per airplane.

We estimate that it will take approximately 1 work hour per airplane to accomplish the inspections specified in Boeing Alert Service Bulletin DC10–22A127, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of these inspections required by this AD on U.S. operators is estimated to be $15,120, or $60 per airplane.

Should an operator be required to perform the follow-on actions specified in Boeing Alert Service Bulletin DC10–22A126, the cost estimates are as follows:

- Condition 2-Repair/inspect: 1 work hour per airplane at $60 per work hour.
- Condition 4-Realign: 1 work hour per airplane at $60 per work hour.
- Condition 5-Replace LVDT: 1 work hour per airplane at $60 per work hour; estimated parts cost of $900.
- Condition 6-Replace hangar: 1 work hour per airplane at $60 per work hour; estimated parts cost of $100.

Should an operator be required to perform the follow-on actions specified in Boeing Alert Service Bulletin DC10–22A127, the cost estimates are as follows:

- Option 1-Replace LVDT and do adjustment/test: 2 work hours per airplane at $60 per work hour; estimated parts cost of $900.
- Option 2-Install a heat shrinkable sleeve and inspect: 2 work hours per airplane at $60 per work hour.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

For the reasons discussed above, I certify that this action (1) is not a

''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2003–11–04 McDonnell Douglas: Amendment 39–13163. Docket 2001–NM–358–AD.

Applicability: Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F, DC–10–30F (KC–10A and KDC–10), DC–10–40, and DC–10–40F airplanes; as listed in Boeing Alert Service Bulletin DC10–22A126, dated October 31, 2001; and Boeing Alert Service Bulletin DC10–22A127, dated December 17, 2001; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the linear variable differential transducers (LVDTs) of the autopilot, which could result in an automatic pitch trim malfunction or an autopilot disconnect, and consequent reduced controllability of the airplane, accomplish the following:

Detailed Inspections/Follow-on Actions

(a) Within 90 days after the effective date of this AD: Do the detailed inspections of the LVDTs of the autopilot for discrepancies as required by paragraphs (a)(1) and (a)(2) of this AD.

Note 2: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

(1) Inspect the LVDTs for affected serial numbers (with undersize nylok elements) per Figure 1 of Boeing Alert Service Bulletin DC10–22A127, dated December 17, 2001, excluding Evaluation Form. If any affected serial number is found, before further flight, do either Option 1 (including replacing the LVDT with a new LVDT and doing an automatic pitch trim adjustment/test), or Option 2 (including installing a heat-shrinkable sleeve over the LVDT jamnut and doing repetitive inspections for any loose jamnut every 500 flight hours until the LVDT is replaced with a new LVDT), of Condition 1 of the service bulletin, per the service bulletin. If any discrepancy is found, before further flight, replace the LVDT with a new LVDT. If no discrepancy is found, no further action is required by this paragraph.

(2) Inspect the shear rivets of the LVDTs of the drive assembly of the automatic pitch trim for discrepancies (shearing and/or looseness), per Boeing Alert Service Bulletin DC10–22A126, dated October 31, 2001, excluding Evaluation Form. If any discrepancy is found, before further flight, do Conditions 2 through 6 (including repairing the driver assembly and inspecting the LVDT within 9 months after doing the repair; doing an automatic pitch trim adjustment/test; aligning the LVDT; replacing the existing LVDT with a new LVDT; and replacing the hangar assembly with a new assembly), as applicable, of the service bulletin, per the service bulletin. If no discrepancy is found, no further action is required by this paragraph.

Part Installation

(b) As of the effective date of this AD, no one may install an LVDT with a serial number listed in the ''Affected Serial Numbers'' table in Figure 1 of Boeing Alert Service Bulletin DC10–22A127, dated December 17, 2001, excluding Evaluation Form, on any airplane.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) The actions shall be done in accordance with Boeing Alert Service Bulletin DC10–22A126, dated October 31, 2001, excluding Evaluation Form; and Boeing Alert Service Bulletin DC10–22A127, dated December 17, 2001, excluding Evaluation Form; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(f) This amendment becomes effective on July 3, 2003.

Issued in Renton, Washington, on May 21, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13223 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 111

[T.D. 03–23]

RIN 1515–AD28

Customs Broker License Examination Dates

AGENCY: Customs and Border Protection, Department of Homeland Security.

ACTION: Interim rule.

SUMMARY: This document sets forth an interim amendment to Part 111 of the Customs Regulations which governs the licensing and conduct of individuals, corporations, and other entities as customs brokers. The amendment involves the addition of a provision that would allow Customs and Border Protection to publish a notice changing the date on which a semi-annual written examination for an individual broker's license will be held when the normal date conflicts with a holiday, religious observance, or other scheduled event.

DATES: Interim rule effective May 29, 2003; comments must be submitted by July 28, 2003.

ADDRESSES: Written comments are to be addressed to the Bureau of Customs and Border Protection, Office of Regulations and Rulings, Attention: Regulations Branch, 1300 Pennsylvania Avenue NW., Washington, DC 20229. Submitted comments may be inspected at the Bureau of Customs and Border Protection, 799 9th Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mike Craig, Office of Field Operations (202–927–1684).

SUPPLEMENTARY INFORMATION:

Background

Section 641 of the Tariff Act of 1930, as amended (19 U.S.C. 1641), provides that a person (an individual, corporation, association, or partnership) must hold a valid customs broker's license and permit in order to transact customs business on behalf of others, sets forth standards for the issuance of broker's licenses and permits, and provides for the taking of disciplinary action against brokers that have engaged in specified types of infractions. In the case of an applicant for an individual broker's license, section 641 provides that the Secretary of the Treasury may conduct an examination to determine the applicant's qualifications for a license. Section 641 also authorizes the Secretary of the Treasury to prescribe rules and regulations relating to the customs business of brokers as may be necessary to protect importers and the revenue of the United States and to carry out the provisions of section 641.

The regulations issued under the authority of section 641 are set forth in part 111 of the Customs Regulations (19 CFR part 111). Part 111 includes detailed rules regarding the licensing of, and granting of permits to, persons desiring to transact customs business as customs brokers, including the qualifications required of applicants and the procedures for applying for licenses and permits. Section 111.11 sets forth the basic requirements for a broker's license and, in paragraph (a)(4), provides that an applicant for an individual broker's license must attain a passing grade on a written examination taken within the 3-year period before submission of the license application prescribed under § 111.12. Section 111.13 sets forth the requirements and procedures for the written examination for an individual broker's license. Paragraph (b) of § 111.13 concerns the date and place of the examination and, in the first sentence, provides that ''[w]ritten examinations will be given on the first Monday in April and October.''

Customs and Border Protection (CBP) notes that the first Monday in October 2003, that is, October 6th, coincides with the observance of Yom Kippur, and CBP further notes that the regulatory text quoted above does not provide for the adoption of alternative examination dates. In order to avoid conflicts with national holidays, religious observances, and other foreseeable events that could limit an individual's opportunity to take the broker's examination, CBP believes that § 111.13(b) should be amended to provide CBP with some flexibility in those circumstances as regards the determination of the specific date on which an examination will be given. Accordingly, this document amends the first sentence of § 111.13(b) to provide for an exception to the general rule when the scheduled examination date conflicts with a national holiday, religious observance, or other foreseeable event and CBP publishes in the **Federal Register** an appropriate notice of a change in the examination date.

Comments

Before adopting this interim regulation as a final rule, consideration will be given to any written comments timely submitted to CBP, including comments on the clarity of this interim rule and how it may be made easier to understand. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552) and § 103.11(b) of the Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Office of Regulations and Rulings, Bureau of Customs and Border Protection, 799 9th Street, NW., Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 572–8768.

Inapplicability of Notice and Delayed Effective Date Requirements and the Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 553(b)(B), CBP has determined that prior public notice and comment procedures on this regulation are unnecessary and contrary to the public interest. The regulatory change provides a benefit to prospective applicants for individual customs broker licenses and imposes no new regulatory burden or obligation on any member of the general public. For the same reasons, pursuant to the provisions of 5 U.S.C. 553(d)(1) and (3), CBP finds that there is good cause for dispensing with a delayed effective date. Because no notice of proposed rulemaking is required for interim regulations, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

This document does not meet the criteria for a ''significant regulatory action'' as specified in E.O. 12866.

Drafting Information

The principal author of this document was Francis W. Foote, Office of Regulations and Rulings, Bureau of Customs and Border Protection. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 111

Administrative practice and procedure, Brokers, Customs duties and inspection, Imports, Licensing, Reporting and recordkeeping requirements.

Amendment to the Regulations

■ For the reasons set forth in the preamble, Part 111 of the Customs Regulations (19 CFR Part 111) is amended as set forth below.

PART 111—CUSTOMS BROKERS

■ 1. The authority citation for Part 111 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States), 1624, 1641.

* * * * *

■ 2. In § 111.13, the first sentence of paragraph (b) is revised to read as follows:

§ 111.13 Written examination for individual license.

* * * * *

(b) *Date and place of examination.* Written examinations will be given on the first Monday in April and October unless the regularly scheduled

examination date conflicts with a national holiday, religious observance, or other foreseeable event and the agency publishes in the **Federal Register** an appropriate notice of a change in the examination date. * * *

* * * * *

Robert C. Bonner,

Commissioner, Customs and Border Protection.

Approved: April 24, 2003.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 03–13455 Filed 5–28–03; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD13–02–020]

RIN 1625–AA00 (Formerly RIN 2115–AA97)

Security Zone: Portland Rose Festival on Willamette River

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a security zone surrounding the City of Portland's Waterfront Park to include all waters of the Willamette River, from surface to bottom, encompassed by the Hawthorne and Steel Bridges during the annual Rose Festival. Terrorist acts against the United States necessitate this action to properly safeguard all vessels participating in the Portland Rose Festival from terrorism, sabotage, or other subversive acts. We anticipate the security zone will have limited effects on commercial traffic and significant effects on recreational boaters; ensuring timely escorts through this security zone is a high priority of the Captain of the Port.

DATES: This rule is effective June 4, 2003.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD13–02–020) and are available for inspection or copying at U.S. Coast Guard Marine Safety Office/Group Portland between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LTJG Tad Drozdowski, c/o Captain of the Port, Portland Oregon at (503) 240–2584.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On January 22, 2003, a notice of proposed rulemaking (NPRM) was published entitled Security Zone: Portland Rose Festival on Willamette River in the **Federal Register** (68 FR 2946). We received one letter commenting on the proposed rule. No public hearing was requested, and none was held.

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**. Waiting 30 days for this rule to be effective is contrary to the public interest. The Captain of the Port has an urgent and critical security need to control the movement of vessels in the vicinity of the Rose Festival. This need is based on the continuing and ongoing terrorist threat against the United States.

The Coast Guard believes that this finding is consistent with the principle of fundamental fairness, which require that all affected persons be afforded a reasonable time to prepare for the effective date of the rulemaking. In 2002 the Coast Guard published a temporary final rule for the Rose Festival in 67 FR 34842 that was substantively identical to this rule. Further, the notice of proposed rulemaking for this rule was published four months prior to the 2003 Rose Festival. Lastly, the security zone in this regulation has been carefully designed to minimally impact the public while providing a reasonable level of protection for the vessels participating in the Rose Festival. For these reasons waiting 30 days for the rule to be enforceable would be impracticable, unnecessary, and contrary to the public interest.

Background and Purpose

This security zone is necessary to provide for the security of vessels participating in the 2003 Portland Rose Festival in the navigable waters of the United States. This rule will be effective less than 30 days after publication in the **Federal Register**.

Discussion of Comments and Changes

There was one comment to this rulemaking. The comment focused on the fact that there is no terrorist threat to the Rose Festival and that this rule will affect recreational boaters.

The Coast Guard has considered this comment and determined that the risk of inaction is outweighed by the risk of action. There are continuing and ongoing terrorist threats against the United States. The Rose Festival is a large gathering of the public that often includes several public vessels from the U.S. Navy and Coast Guard. This rule is designed to minimally impact the public, including recreational boaters, while providing a reasonable level of protection for the public and public vessels. Accordingly, no changes were made to the rule.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DHS is unnecessary.

This expectation is based on adequate resources allowing vessel approvals from the Captain of the Port or his designated representatives to transit through the regulated area. For the above reasons, the Coast Guard only anticipates minor economic impact.

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 proposed 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 this portion of the Willamette River. The likely impacts to small entities would include minor time delays, potential inspections, and possibly non-entrance if the Captain of the Port or his designated representatives sense the vessels participating in the Rose Festival are threatened. The security zone will not have a significant economic impact because adequate resources will allow vessels timely approval from the Captain of the Port or his designated

representatives to transit through the regulated area.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. A notice of proposed rulemaking was published in January to accommodate mariners by giving them proper notice and to provide a forum for their comments, questions, and concerns.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because the temporary security zone would not last longer than one week in duration. The temporary security zone would be established on Wednesday, June 4 with the arrival of the first vessel to the City of Portland's Waterfront Park and extend until the last vessel departs the Waterfront Park on Monday, June 9. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.

■ 2. Add § 165.1312 to read as follows:

§ 165.1312 Security Zone; Portland Rose Festival on Willamette River.

(a) *Location.* The following area is a security zone: All waters of the Willamette River, from surface to bottom, encompassed by the Hawthorne and Steel Bridges.

(b) *Regulations.* In accordance with § 165.33, entry into this zone is prohibited unless authorized by the Coast Guard Captain of the Port, Portland or his designated representatives. Section 165.33 also contains other general requirements.

(c) *Authority.* In addition to 33 U.S.C. 1231, the authority for this section includes 33 U.S.C. 1226.

(d) *Enforcement period.* This section normally will be enforced from the first Wednesday of June to the next Monday in June. In 2003 this section will be enforced from June 4 to June 9. After 2003, a notice of enforcement normally will be published in the **Federal Register** 30 days prior to the beginning of the event.

Dated: May 13, 2003.

P.D. Jewell,

Captain, U.S. Coast Guard, Captain of the Port, Portland.

[FR Doc. 03–13443 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7505–1]

Utah: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of immediate final rule.

SUMMARY: We are withdrawing the immediate final rule for Utah: Final Authorization of State Hazardous Waste Management Program Revision published on April 10, 2003, which approved the tenth revision to Utah's Hazardous Waste Rules. We stated in the immediate final rule that if we received comments that oppose this authorization, we would publish a timely notice of withdrawal in the **Federal Register**. Subsequently, we received comments that oppose this action. We will address these comments in a subsequent final action based on the proposed rule also published on April 10, 2003, at 68 FR 17577.

DATES: As of May 29, 2003, we withdraw the immediate final rule published on April 10, 2003, at 68 FR 17556.

FOR FURTHER INFORMATION CONTACT: Kris Shurr (8P–HW), phone number: (303) 312–6312, 999 18th Street, Suite 300, Denver, Colorado 80202–2466, email: *shurr.kris@epa.gov.*

SUPPLEMENTARY INFORMATION: Because we received comments that oppose this authorization, we are withdrawing the immediate final rule for Utah: Final Authorization of State Hazardous Waste Management Program Revision published on April 10, 2003, at 68 FR 17556, which intended to grant authorization for the tenth revision to Utah's Hazardous Waste Rules. We stated in the immediate final rule that if we received comments that opposed this action, we would publish a timely notice of withdrawal in the **Federal Register**. Subsequently, we received comments that opposed this action. We will address all comments in a subsequent final action based on the proposed rule previously published on April 10, 2003, at 68 FR 17577. We will not provide for additional public comment during the final action.

Dated: May 19, 2003.

Wanda C. Taunton,

Acting Regional Administrator, Region VIII.

[FR Doc. 03–13427 Filed 5–28–03; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 020603140–3129–03, I.D. 050102G]

RIN 0648–AQ00

Regulations Governing the Taking and Importing of Marine Mammals; Eastern North Pacific Southern Resident Killer Whales

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

ACTION: Final rule.

SUMMARY: Following a review of the status of the eastern North Pacific Southern Resident stock of killer whales (Orcinus orca), NMFS has determined that the stock is below its Optimal Sustainable Population (OSP) and, therefore, is depleted as defined in the Marine Mammal Protection Act (MMPA). This action is a step in the process to address the decline in the number of Southern Resident killer whales. NMFS also announces the preparation of a Conservation Plan to reverse the decline and to promote recovery of the stock to OSP.

DATES: Effective June 30, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. Garth Griffin, Northwest Regional Office, NMFS, Portland, OR (503) 231–2005, or Dr. Thomas Eagle, Office of Protected Resources, NMFS, Silver Spring, MD (301) 713–2322, ext. 105.

SUPPLEMENTARY INFORMATION:

Electronic Access

A list of the references used in this notice and other information related to the status of this stock of killer whales is available on the Internet at <*http://www.nwr.noaa.gov/mmammals/whales/proposal.htm.*>

Background

Section 3(1)(A) of the MMPA (16 U.S.C. 1362(1)(A)) defines the term, ''depletion'' or ''depleted,'' as any case in which ''the Secretary, after consultation with the Marine Mammal Commission and the Committee of Scientific Advisors on Marine Mammals ... determines that a species or population stock is below its optimum sustainable population [(OSP)].'' Section 3(9) of the MMPA defines OSP ''...with respect to any population stock, [as] the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity [(K)] of the habitat and the health of the ecosystem of which they form a constituent element.'' NMFS' regulations at 50 CFR 216.3 clarify the definition of OSP as a population size which falls within a range from the population level of a given species or stock that is the largest supportable within the ecosystem (carrying capacity [K]) to the population level that results in the maximum net productivity level (MNPL). MNPL is the greatest net annual increment (increase) in population numbers resulting from additions due to reproduction less losses due to natural mortality.

A population stock below its MNPL is, by definition, below OSP and thus would be considered depleted under the MMPA. Historically, the estimated MNPL has been expressed as a range of values, generally 50 to 70 percent of K (42 FR 12010, March 1, 1977). In 1977, the midpoint of this range (60 percent of K) was used to determine whether dolphin stocks in the eastern tropical Pacific Ocean were depleted under the MMPA (42 FR 64548, December 27, 1977). The 60–percent-of-K value was used in the final rule governing the taking of marine mammals incidental to commercial tuna purse seine fishing in the eastern tropical Pacific Ocean (45 FR 72178, October 31, 1980) and has been used since that time for other status reviews under the MMPA. For stocks of marine mammals, including killer whales, K is generally unknown. NMFS, therefore, has used the best estimate available of maximum historical abundance as a proxy for K.

On May 2, 2001, NMFS received a petition from the Center for Biological Diversity and 11 co-petitioners to list Southern Resident killer whales under the Endangered Species Act (ESA). After conducting a status review to consider the information in the petition and other information related to the status of Southern Resident killer whales, NMFS determined that listing these killer whales as a threatened or endangered species was not warranted at this time because Southern Resident killer whales did not constitute a species as defined by the ESA. Scientific information evaluated during the status review, however, indicated that the population stock may be depleted under the MMPA.

As required by the MMPA, NMFS initiated consultation with the Marine Mammal Commission (Commission) in a letter dated June 25, 2002, and began the process for determining if the stock was depleted. The Commission responded to NMFS in a letter dated November 18, 2002, with

recommendations to: (1) prepare research plans for killer whales in the North Pacific, particularly to collect specific information needed to re-evaluate the status of Southern Resident killer whales within four years; (2) to proceed with the depletion determination; and (3) to identify and implement needed actions to protect important habitat as a conservation plan is developed for the Southern Resident killer whale stock. In a subsequent letter, dated March 31, 2003, the Commission: (1) reiterated its recommendation to designate the stock as depleted; (2) recommended that NMFS should thoroughly review information related to historical abundance and other information to establish recovery goals during conservation planning; and (3) recommended that NMFS prepare a conservation plan as soon as possible and, in the interim, initiate any conservation measures identified to date.

Pursuant to section 115 of the MMPA (16 U.S.C. 1383b), NMFS published an advance notice of proposed rulemaking (ANPR) (67 FR 44132, July 1, 2002) which included a request for scientific information. Specifically, the ANPR requested information, comments, and supporting documents on stock status, areas of significance to the stock, and any factors that may be causing the decline or impeding the recovery of the stock. After considering comments received in response to the ANPR and the recommendations of the Commission, NMFS published a proposed rule to designate the Southern Resident stock as depleted (68 FR 4747, January 30, 2003) and solicited comments on the proposal and on potential conservation measures that may benefit these whales. The 60–day comment period on the proposed rule closed on March 31, 2003. A summary of the public comments received and the agency's responses is presented below.

Comments and Responses

NMFS received 38 comments in response to the proposed rule. Eleven of these comments voiced opinion on the status of Southern Resident killer whales relative to the Endangered Species Act. Summaries and responses are provided below for those substantive comments that address the proposed depleted designation or the potential conservation measures for the benefit of Southern Resident killer whales under the MMPA.

Comment 1: Twenty-four commenters either supported NMFS' proposal to designate the Southern Resident stock of killer whales as depleted or agreed that the stock meets the statutory definition of depleted.

Response: The agency agrees with the comments.

Comment 2: One commenter questioned how NMFS could establish an OSP level for Southern Resident killer whales when both ''resident'' and ''non-resident'' types use the same areas.

Response: By definition, the upper and lower bounds of OSP are estimated for discrete stocks of marine mammals. NMFS recognizes Southern Resident killer whales as a separate stock of killer whales under the MMPA based upon genetic, behavioral, and ecological information. Therefore, NMFS must evaluate the status of Southern Resident killer whales relative to its OSP even though other stocks of killer whales are sometimes found in Puget Sound. Because researchers can distinguish between Southern Residents and other types of killer whales and there are ecological differences between residents and non-residents, the periodic overlap of Southern Resident and other killer whales within Puget Sound does not confound the estimation of the OSP levels for Southern Resident killer whales.

Comment 3: Twenty-one commenters included thoughts on factors that may be contributing to population decline. Pollution and related effects dominated the majority of comments on factors for decline and suggested subjects for the development of conservation measures, but a number of other potential stresses to the population were also identified. The summary of issues related to pollution includes: bio-accumulation of persistent chemical contaminants and heavy metals; non-point source contamination from commercial and residential development affecting salmon runs and bait fish survival; over use of pesticides, fertilizer, creosoted pilings and railroad ties, chemical cleaners and auto care products; agricultural run-off and pet waste; depleted uranium dumping; and oil spills and petroleum/fossil fuel discharges or exhaust. Among the remaining issues identified as possibly contributing to the decline of killer whales are: infectious diseases; over fishing on orca prey species or smaller forage fishes; shoreline modifications that reduce fish habitat; dams that block salmon passage or contribute to salmon mortality; noise and stress associated with shipping and vessel activities including commercial traffic, military operations and whale watching; indiscriminate release of real time killer whale sighting information for use by boaters; and the expansion of commercial fall/winter whale watching into central and southern Puget Sound. A number of ideas for addressing these concerns, including regulatory and non-regulatory approaches, were also received.

Response: With this notice, NMFS is announcing its intent to prepare a Conservation Plan to assist in restoring the Southern Resident stock. The comments received in response to the proposal will help NMFS to define the scope of the planning effort to build a comprehensive recovery strategy. NMFS will seek continued stakeholder support and co-manager participation as it develops the content for the conservation plan.

Comment 4: Six commenters supported research efforts to close gaps in the available information about the Southern Resident population and their habitat. Areas for research include questions regarding: killer whale taxonomy; the effects of disease; the effects of anthropogenic underwater noise associated with vessel traffic or naval sonar activities; historic versus current contaminant load in killer whale tissues; killer whale feeding ecology and prey abundance/distribution; year round orca range determination; and shoreline resources and nearshore habitats that are vulnerable to oil spills and may be degraded thereby contributing to reduced productivity for forage species.

Response: In spite of the volume of scientific information available on the Southern Resident stock, NMFS acknowledges that significant data gaps still exist in a number of areas. Little is known of the diseases affecting this population. Research into the effects of sound in the marine environment, including sonar, on whales and other marine mammals is ongoing but incomplete. Research is necessary to fill the gaps and improve our understanding of this population and the factors that may affect its recovery. Accordingly, NMFS has developed an initial list of research priorities and has begun several studies to answer some of the outstanding questions. It is anticipated that additional research needs will be identified during the development of conservation measures associated with the preparation of the Conservation Plan.

Determination of ''Population Stock'' or ''Stock''

Section 3(11) of the MMPA defines a population stock or stock as a group of marine mammals of the same species or smaller taxa in a common spatial arrangement, that interbreed when

mature. Although this definition is in part a legal concept, stocks, species, and populations are biological concepts that must be defined on the basis of the best scientific data available.

All extant forms of killer whales are currently classified as the same biological species, *O. orca*. Three forms, Resident, Transient and Offshore, have been identified along the west coast of North American and vary in morphology, ecology, behavior, group size, social organization, acoustic repertoire, and genetic characteristics. A summary of information on the different forms was presented in the proposed rule (68 FR 4747, January 30, 2003).

Specific stock definitions for west coast killer whales are provided in the U.S. Pacific Marine Mammal Stock Assessments (Carretta et al. 2001) and include consideration of data on association patterns, acoustics, movements, genetic differences and potential fishery interactions. Five killer whale stocks are recognized within the Pacific U.S. exclusive economic zone: 1) the eastern North Pacific Northern Resident stock; 2) the eastern North Pacific Southern Resident stock; 3) the eastern North Pacific Transient stock; 4) the eastern North Pacific Offshore stock; and 5) the Hawaiian stock. Eastern North Pacific Southern Residents occur in the inland waterways of southern British Columbia and Washington, including the Georgia Strait, the Strait of Juan de Fuca, and Puget Sound.

Determination as Depleted Under the MMPA

While there are no empirical estimates of the historical stock size for Southern Resident killer whales, NMFS examined indirect evidence to derive an estimate of historical abundance for the population. A minimum historical abundance of 140 whales was derived by combining the total abundance based upon the original 1974 census population (71) with the estimated number of animals that were removed or died (68) during live capture operations for display conducted in the 1960s and early 1970s (67 FR 44132, 44133, July 1, 2002). The number of animals that may have been killed by shooting or other human interactions is unknown but, based on anecdotal evidence, is likely to have been greater than zero. Additionally, a comparison of genetic diversity with the larger Northern Resident killer whale stock (214 whales) indicates that the Southern Resident stock may have been of similar size in the recent past (Barrett-Lennard, L.G. and Ellis, G.M. 2001 and Krahn, M.M., *et al.* 2002). Therefore, the best available scientific information suggests that the minimum estimate of historical abundance is approximately 140 whales, and the genetic evidence suggests it may have been about 200 whales. However, the actual historical abundance may have been higher than these two estimates.

The abundance of the Southern Resident stock has declined by approximately 20 percent over the past 6 years (1996–2002)(Krahn, M.M., *et al.* 2002). The true K and MNPL are unknown for Southern Resident killer whales. Using an estimated range of historical stock size of 140–200 whales as a proxy for K, the estimated MNPL for the Southern Resident stock would be 84–120 whales (i.e., 60 percent of 140–200). A more complete discussion of the estimated historical stock size can be found in the ANPR referenced above. The 2002 abundance of 80 Southern Resident killer whales (Center for Whale Research, 2002 Orca Survey) is below the lower bound of the estimated MNPL range (84) for the stock. The current population size meets the statutory definition of a depleted stock. NMFS recognizes that the current population size is very near the estimated lower bound of MNPL for this stock but is taking this risk averse approach in light of recent declines. Therefore, based on the best scientific information available and consultation with the Commission, NMFS determines that the Southern Resident stock of killer whales is depleted under the MMPA.

Conservation Plan

Section 115(b) of the MMPA (16 U.S.C. 1383b(b)(1)(C)) provides that a Conservation Plan shall be prepared as soon as possible, following a depleted designation, unless it is determined that such a plan will not promote the conservation of the species or stock. NMFS, after consultation with the Marine Mammal Commission, has determined that a Conservation Plan will assist in the conservation of the stock and is expediting the preparation of such a plan concurrent with the publication of this action.

NMFS, as part of the proposed rule, requested public comment on: areas of ecological significance (mating, rearing, resting, feeding) to the eastern North Pacific Southern Resident stock; impacts that may be causing the decline or impeding the recovery of the stock; and potential conservation measures that may be useful in alleviating those impacts. Information was also solicited on the potential economic impacts and the potential biological benefits of alternative conservation measures. NMFS will use the information collected in response to the proposed rule for the development of conservation measures and in the preparation of the Conservation Plan. To promote and implement an open public dialogue concerning stock conservation and rebuilding measures, NMFS will hold public meetings beginning in May to obtain the views of stakeholders, scientists, advocacy groups, and the general public to aid in identifying the elements of a successful Conservation Plan. NMFS will advise the public on the progress of and opportunities to participate in the conservation planning process.

References

A complete list of all cited references is available via the Internet (see Electronic Access) or upon request (see **ADDRESSES**).

Classification

This final rule has been determined to be not significant for the purposes of Executive Order 12866. Depletion designations under the MMPA are similar to ESA listing decisions, which are exempt from the requirement to prepare an environmental assessment or environmental impact statement under the National Environmental Policy Act. See NOAA Administrative Order 216–6.03(e)(1). Thus, NMFS has determined that the depletion designation of this stock under the MMPA is exempt from the requirements of the National Environmental Policy Act of 1969, and an Environmental Assessment or Environmental Impact Statement is not required.

The Assistant General counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. No comments were received regarding this certification. As a result, no regulatory flexibility analysis was prepared.

This rule does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act of 1980. This rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 13132.

List of Subjects in 50 CFR Part 216

Administrative practice and procedure, Exports, Imports, Marine mammals, Transportation.

Dated: May 20, 2003.

Rebecca Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

■ For the reasons set out in the preamble, 50 CFR part 216 is amended as follows:

PART 216–REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

1. The authority citation for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

■ 2. In § 216.15, a new paragraph (h) is added to read as follows:

§ 216.15 Depleted species.

* * * * *

(h) Eastern North Pacific Southern Resident stock of killer whales (Orcinus orca). The stock includes all resident killer whales in pods J, K, and L in the waters of, but not limited to, the inland waterways of southern British Columbia and Washington, including the Georgia Strait, the Strait of Juan de Fuca, and Puget Sound.

[FR Doc. 03–13421 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 021219321–2321–01; I.D. 120901A]

RIN 0648–AQ39

Atlantic Highly Migratory Species; Commercial Shark Management Measures

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

ACTION: Emergency rule; extension of expiration date; request for comments; fishing season notification.

SUMMARY: NMFS extends the expiration date of the emergency rule that established the commercial annual quotas for ridgeback and non-ridgeback large coastal sharks (LCS) at 783 metric tons (mt) dressed weight (dw) and 931 mt dw, respectively; established the commercial annual quota for small coastal sharks (SCS) at 326 mt dw; and suspended the regulation regarding the commercial ridgeback LCS minimum size. NMFS clarifies that the provision to count dead discards against the commercial quota applies to dead discards by HMS fishermen only. NMFS also notifies eligible participants of the opening and closing dates for the second semi-annual 2003 Atlantic LCS, SCS, pelagic shark, blue shark, and porbeagle shark fishing seasons. This emergency rule extension is necessary to ensure that the regulations in force are based on the best available science.

DATES: The expiration date of the emergency rule published December 27, 2002 (67 FR 78990), is extended to December 29, 2003.

The fishery opening for ridgeback and non-ridgeback LCS is effective July 1, 2003, through 11:30 p.m., local time, September 15, 2003. The ridgeback and non-ridgeback LCS closures are effective from 11:30 p.m., local time, September 15, 2003, through December 31, 2003. The fishery opening for SCS, pelagic sharks, blue sharks, and porbeagle sharks is effective July 1, 2003, through December 31, 2003, unless otherwise modified or superseded through publication of a closure notice in the **Federal Register**.

Comments on this action must be received no later than 5 p.m. on July 14, 2003.

ADDRESSES: Written comments on this action must be mailed to Christopher Rogers, Chief, NMFS Highly Migratory Species Management Division, 1315 East-West Highway, Silver Spring, MD 20910; or faxed to 301–713–1917. Comments will not be accepted if submitted via email or the Internet. Copies of the Environmental Assessment and Regulatory Impact Review (EA/RIR) prepared for the initial emergency rule and copies of the supplemental EA prepared for this extension may be obtained from Karyl Brewster-Geisz at the same address or may be obtained on the web at *http://www.nmfs.noaa.gov/sfa/hmspg.html*.

FOR FURTHER INFORMATION CONTACT: Karyl Brewster-Geisz or Chris Rilling at 301–713–2347.

SUPPLEMENTARY INFORMATION: The Atlantic shark fisheries are managed under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Fishery Management Plan for Atlantic Tunas, Swordfish, and Sharks (HMS FMP) is implemented by regulations at 50 CFR part 635.

On May 8, 2002, NMFS announced the availability of the first SCS stock assessment since 1992 (67 FR 30879). The Mote Marine Laboratory and the University of Florida provided NMFS with another SCS stock assessment in August 2002. Both these stock assessments indicate that overfishing is occurring on finetooth sharks. The three other species in the SCS complex (Atlantic sharpnose, bonnethead, and blacknose) are not overfished and overfishing is not occurring.

On October 17, 2002, NMFS announced the availability of the LCS stock assessment (67 FR 64098), which currently constitutes the best available science for LCS. The results of this stock assessment indicate that the LCS complex is still overfished and overfishing is occurring; that sandbar sharks are no longer overfished but that overfishing is occurring; and that blacktip sharks are rebuilt and overfishing is not occurring. The peer review process for the 2002 LCS stock assessment, required under the December 2000 settlement agreement with commercial fishermen, was completed in mid-December, 2002.

As a result of these stock assessments, NMFS published an emergency rule on December 27, 2002 (67 FR 78990), that implemented management measures based on the best available science. The December 2002 emergency rule expires on June 30, 2003.

This extension to the December 2002 emergency rule (1) maintains the commercial annual quotas for ridgeback and non-ridgeback LCS at 783 mt dw and 931 mt dw, respectively; (2) maintains the commercial annual quota for SCS at 326 mt dw; and (3) continues to suspend the regulation regarding the commercial ridgeback LCS minimum size. This emergency rule does not affect commercial management measures for pelagic sharks and does not affect the management measures for prohibited species or recreational fisheries.

The extension is necessary to manage and conserve LCS and SCS based on the best scientific information available. Without this emergency rule extension, the reduced LCS and SCS commercial quotas of 816 mt dw and 329 mt dw, respectively, adopted in the HMS FMP and based on the 1998 LCS stock assessment, would be in force, inconsistent with the terms of the court-approved settlement agreement and with National Standard 2 of the Magnuson-Stevens Act. The settlement agreement with commercial fishermen explicitly provided that NMFS could adjust LCS quotas and other management measures in the 1999 HMS FMP based on the 2002 LCS stock assessment after completion of a peer review process, but could take emergency action as needed based on the assessment pending completion of the review process.

NMFS is developing Amendment 1 to the HMS FMP for Atlantic sharks in response to the new stock assessments.

NMFS recently completed scoping hearings on Amendment 1 to the HMS FMP and is developing a proposed rule for public review and comment. The proposed rule should be available during the summer of 2003 and the final rule should be effective by January 1, 2004.

Comments and Responses

NMFS conducted four public hearings on the emergency rule (68 FR 1024, January 8, 2003) and received many written and oral comments over a 50 day comment period. In addition, HMS Advisory Panel members provided NMFS with comments specific to the shark emergency rule at a meeting in Silver Spring, Maryland on February 10–12, 2003. Comments were submitted by recreational and commercial fishing organizations, state agencies, conservation groups, and the general public. The following is a summary of the major comments together with NMFS' responses. The comments are arranged by topic similar to the organizational structure of the EA/RIR.

LCS Commercial Annual Quota

Comment 1: The LCS quota established by the December 27, 2002, emergency rule is 2 million pounds dw less than the 1996 quota. The 1996 quota level would be available now if NMFS had assessed certain species of shark such as bull, dusky, silky, spinner, three species of hammerheads, and tiger. This is especially true given that dusky and tiger sharks, in particular, have shown large increases in catch lately.

Response: The status of the LCS stock and the quota set in the emergency rule are based on the results of the 2002 LCS stock assessment which represents the best available science. The stock assessment was conducted for individual species for which there was sufficient information and for the complex as a whole to account for other species. The information from the stock assessment on the LCS complex as a whole indicates the LCS complex is overfished and that overfishing is occurring. This result does not warrant an increase in quotas for the species mentioned. Information may be available to conduct a stock assessment on dusky sharks in the future.

Comment 2: The NMFS EA/RIR failed to describe which models were used to arrive at the quota levels. The EA/RIR did not provide the justification for choosing certain models. Additionally, NMFS did not acknowledge that uncertainty levels are high. NMFS should establish formal criteria for selecting appropriate models for determining quotas prior to completion of the stock assessment and not after. Also, NMFS should consider incorporating formal decision analysis techniques as part of the stock assessment.

Response: NMFS relied on overall conclusions and findings of the stock assessment to determine quota levels consistent with the status of stocks. Similarly, determinations as to whether a stock is overfished or whether overfishing is occurring are based on the overall conclusions and findings of the stock assessment. The conclusions and findings of the stock assessment are based on balancing the results of all models, the appropriate application of the models, the sensitivity of the models to the data, and the convergence of the models. NMFS will consider formally identifying the criteria used to balance the results of the models in advance of the next stock assessment.

Comment 3: Increasing the LCS quota was unjustified and could result in an increase in effort, which in turn, could result in an increase in bycatch of sharks and protected species.

Response: NMFS set the ridgeback quota on a slightly reduced level from the average ridgeback harvest, based on average landings of each species, as a precautionary measure to ensure the species in the ridgeback LCS group, other than sandbar sharks, do not decline further. A similar process was followed to ensure that the non-ridgeback LCS, other than blacktip and spinners, do not decline further. The addition of 20 percent to the blacktip portion of the non-ridgeback quota level corresponds to the lower end of the increase suggested for blacktip sharks by the 2002 LCS stock assessment. NMFS does not expect the LCS quotas established in the emergency rule to result in increased fishing effort. From 1999 to 2001, the average LCS landings for all fishermen, including fishermen fishing in state waters, has been 1,693 mt dw and has ranged from 1,616 to 1,778 mt dw. The total ridgeback and non-ridgeback quota under the emergency rule is within this range of recent landings at 1,714 mt dw. Under this landings level, the stock assessment found that the status of the LCS complex as a whole has improved since 1998. Because a number of states now close state waters with the closure of federal waters, because state landings are considered in LCS quota monitoring, and because federal permits are under a limited access system, NMFS does not expect an increase in LCS landings or effort or an increase in non-target finfish or protected species impacts.

Comment 4: The LCS quota appears to be appropriate and does not pose significant risk to the continued rebuilding of the sandbar shark or the LCS complex. Additionally, experience shows that fishermen can target and produce catches that are largely dominated by blacktip sharks.

Response: NMFS agrees. As described in response to comment 2, NMFS believes the quotas are appropriate.

Commercial LCS Size Limits

Comment 1: The method of measuring ridgeback sharks described in the final rule for the HMS FMP (64 FR 29090, May 28, 1999) will not work properly.

Response: This extension to the emergency rule suspends the minimum size requirement. NMFS will re-consider this comment when developing management alternatives for Amendment 1 to the HMS FMP.

Comment 2: NMFS should provide an explanation as to why the ridgeback minimum size was lifted.

Response: The ridgeback minimum size requirement was finalized in the 1999 HMS FMP based in part on the status of sandbar sharks according to the 1998 LCS stock assessment. Due to a lawsuit by the commercial fishing industry, the regulation was never implemented. In 2002, NMFS conducted another LCS stock assessment that found that sandbar sharks were no longer overfished. Given that sandbar sharks are rebuilding without a minimum size requirement and given that implementation of a minimum size requirement can increase discards of sandbar and other sharks, NMFS believes that implementation of a minimum size could slow rebuilding of sandbar sharks and other LCS. NMFS will re-examine in Amendment 1 to the HMS FMP the implications, including those regarding dead discard, of implementing the minimum size in the commercial fishery.

SCS Commercial Annual Quota

Comment 1: The SCS quota should not have been reduced because the assessment for finetooth sharks was incomplete and NMFS needs to gather more information about this species.

Response: A stock assessment for SCS was completed in 2002. This stock assessment examined all SCS individually and as a whole complex and found that overfishing is occurring on finetooth sharks. While the stock assessment states that findings for finetooth sharks should be regarded more cautiously from the results for some of the other species because it used shorter catch-per-unit-effort series and it lacked some bycatch estimates

and catches in some years, the results of the stock assessment are still considered the best available science and NMFS must manage the fishery accordingly. In Amendment 1 to the HMS FMP, NMFS plans to examine the available information for finetooth and other SCS to determine the sources of fishing mortality and consider other alternatives, such as time/area closures, that may reduce fishing effort on finetooth sharks while minimizing impacts on the SCS fishery.

Comment 2: Because finetooth, blacknose, and bonnethead may not be legally taken by recreational fishermen in federal or state waters because they do not reach the 4.5 foot FL size limit, commercial fishermen should be allowed to land more.

Response: The SCS quota capped landings at the highest level of landings by commercial fishermen, including fishermen fishing in state waters. This quota cap was implemented to ensure fishing effort did not increase on finetooth sharks pending Amendment 1 to the HMS FMP.

Comment 3: NMFS estimates of shark bycatch in the shrimp trawl fleet would exceed the annual quota for SCS.

Response: NMFS acknowledges the incorrect estimates provided in the EA/RIR and clarifies in this emergency rule extension that only dead discards from HMS fisheries will be counted against the federal commercial SCS quota. Bycatch and discards in non-HMS fisheries are considered in the stock assessment. NMFS will work with the appropriate management body to minimize shark bycatch in those fisheries, to the extent practicable.

Accounting for all Fishing Mortality

Comment 1: Dead discards should not be counted against future shark quotas. The number of dead discards should only be used in stock assessments that set quotas, in order to prevent confusion among fishermen.

Response: Dead discards are used in stock assessments to determine the current level of fishing mortality and the status of the stocks. The stock assessment does not set the quota; instead the stock assessment provides estimates on the current rate of fishing mortality, the current biomass level, the rate of fishing mortality that the stock may be able to withstand, and the biomass level that could support maximum sustainable yield. From those estimates, NMFS can calculate a total allowable catch level. The quota level set in this emergency rule should be considered a commercial total allowable catch, including all state and federal landings and dead discards in HMS fisheries. NMFS is considering other methods for setting commercial landings quotas in Amendment 1 to the HMS FMP.

Comment 2: NMFS should be commended for including state landings and dead discards in the quota. However, NMFS has not demonstrated that raising the quota to account for state landings and discards will not increase landings further.

Response: The LCS ridgeback and non-ridgeback quotas in the emergency rule are based on average landings from 1999 to 2001 including landings after federal closures. Any state landings and dead discards by HMS fishermen will be counted against the federal commercial quota. Additionally, if the catch quota is exceeded, the quota for the following year will be reduced. Similarly, dead discards will also reduce the quota in future years. Thus, overall landings should not increase. As described above, because a number of states now close state waters with the closure of federal waters, because state landings are considered in LCS quota monitoring, and because federal permits are under a limited access system, NMFS does not expect an increase in LCS landings or effort or an increase in non-target finfish or protected species impacts.

Comment 3: NMFS should explain why accounting for dead discards will not take effect until 2005.

Response: There is a time lag between the season closure dates and when all final landings are reported, entered into a database, and checked for quality control. Logbook data being reported in 2003 will not be fully entered and checked until late spring/early summer 2004. At that time, NMFS will attempt to verify logbook data with dealer and observer reports. However, the actual amount of dead discards for 2003 will not be available until after the fishing seasons for 2004 have begun or ended. Thus, dead discards from 2003 cannot be used to adjust the catch quota until 2005.

Seasonal Quota Adjustments

Comment 1: NMFS should consider staggered closure dates. Closing the fishery early would allow NMFS to tally the catch to date and then reopen it if there is quota remaining.

Response: NMFS has tried this approach in the past and received numerous complaints from fishermen. Because most shark fishermen are permitted in numerous fisheries, after the shark season is closed, many of them refit their vessels to fish for other species. If NMFS then reopens the fishery, fishermen once again need to refit their vessels. Additionally, staggered closure dates with no advanced notice of when or if the fishery will reopen makes it difficult for fishermen to maintain a market niche. NMFS may examine this issue in Amendment 1 to the HMS FMP or in a future rulemaking.

Comment 2: NMFS should consider moving the season start date from July 1 to June 1 for better market opportunities during the Forth of July holiday season. Similar consideration should be given to moving the January 1 start date to December 1.

Response: Changing the season start date may have ecological and economic impacts. An analysis of these impacts needs to be fully considered by the public and NMFS before implementation. NMFS may consider changing season start dates in Amendment 1 to the HMS FMP or in a future rulemaking.

Comment 3: The seasons for ridgeback and non-ridgeback LCS are out of sync with one another and will result in additional discards. NMFS should set a single season closure date for both ridgeback and non-ridgeback LCS. This would also help with enforcement of fishing season closures.

Response: The opening and closure dates for ridgeback and non-ridgeback LCS are based in part on catch rates in previous years. When setting the opening and closure dates, NMFS also considered the fact that, even though fishermen can target certain species, ridgeback LCS could be discarded during the non-ridgeback LCS season. NMFS may consider a single season closure and other options in Amendment 1 to the HMS FMP.

Bycatch and Prohibited Species

Comment 1: NMFS should consider time/area closures to protect juvenile sharks.

Response: Time/area closures may have ecological and economic impacts. The impacts of any closures need to be fully considered by the public and NMFS before implementation. Additionally, some time/area closures to protect juvenile sharks may require coordination with states. NMFS may consider time/area closures as part of Amendment 1 to the HMS FMP.

Comment 2: The LCS fishery should be closed in April to protect pregnant females and pups.

Response: NMFS is considering several alternatives to protect pregnant female sharks and pups in Amendment 1 to the HMS FMP. These alternatives include time/area closures, regional quotas, and changing fishing season start dates.

Comment 3: Dusky sharks are of particular concern due to incidental mortality. This mortality will continue as long as there is a directed shark fishery that is unable to selectively fish certain species. NMFS should conduct a thorough evaluation and reporting of the incidental mortalities of prohibited and overfished species occurring in the fishery.

Response: NMFS believes that many fishermen target certain species of sharks. However, bycatch of other species is inevitable. The latest observer report for the bottom longline fishery indicates that dusky sharks represent approximately one percent of the total shark catch. In Amendment 1 to the HMS FMP, NMFS is considering options to reduce bycatch in the shark fishery.

Comment 4: NMFS should reconsider the prohibition of dusky sharks, and several other coastal shark species such as the Atlantic angel, bignose, Caribbean reef, Caribbean sharpnose, and night sharks. NMFS should set a bycatch quota of 100,000 pounds dw for bignose sharks.

Response: As noted above, according to the latest observer report for the bottom longline fishery, dusky sharks comprise approximately one percent of the total shark catch. The other species listed are either not observed caught or comprise less than one percent of total shark catch in aggregate. NMFS may consider several options to address prohibited species and reduce bycatch as part of Amendment 1 to the HMS FMP.

Comment 5: Dusky, night, and sand tiger sharks are so depleted that they are considered candidates for listing under the Endangered Species Act (ESA). NMFS should assess and reduce unintentional bycatch of these species.

Response: NMFS will be considering various options in Amendment 1 to the HMS FMP to reduce bycatch, as required by the Magnuson-Stevens Act. NMFS recently completed a status review under ESA for dusky sharks and hopes to complete status reviews for night and sand tiger sharks in the near future. The results of the dusky shark status review indicated that recent years have shown an increase in abundance but that catch rates are still much lower than catch rates in the late seventies and early eighties.

Comment 6: NMFS should consider slot sizes to protect large females.

Response: NMFS is examining several options to reduce bycatch as part of Amendment 1 to the HMS FMP. NMFS may consider this option at that time.

General

Comment 1: State regulations should mirror federal regulations, particularly with regard to closures.

Response: NMFS agrees and will work with states during and after the amendment process in order to reach this goal.

Comment 2: The emergency rule sidestepped the process of giving the public an opportunity to comment on management decisions.

Response: NMFS agrees that the public should be given every opportunity to comment on management decisions. The current emergency rule was necessary because, once the December 2001 emergency rule expired, certain measures from the 1999 HMS FMP, which were no longer based on the best available science, would have gone into place unless regulations were promulgated to replace them. While prior notice and comment were impracticable in this case, NMFS held four public hearings on the emergency rule, received comments from the HMS Advisory Panel members at a February 2003 meeting, and gathered significant public input which was considered in the decision to extend the emergency rule.

Comment 3: NMFS should not have proceeded with new quotas before peer reviews were complete. The peer reviews did not endorse raising the LCS quota.

Response: The peer review process, per the settlement agreement with the commercial industry, was not complete until mid-December 2002. If NMFS had waited for the peer reviews before moving forward with a rule, the commercial regulations in the HMS FMP would have gone into place, contrary to National Standard 2 of the Magnuson-Stevens Act. Those regulations in the HMS FMP could have caused substantial harm to the fishing industry. NMFS did consider the peer reviews of the 2002 LCS stock assessment once they were available and found that they were generally positive and supported the 2002 LCS stock assessment. Additionally, the peer reviews themselves were not intended to endorse quota recommendations, but rather to provide an unbiased review of methodology and appropriateness of stock assessment models and interpretation of those models. All peer reviews concluded that the models and methodology used were appropriate. Had the peer reviews been negative or concluded that models were inappropriate, NMFS would have acted immediately to revise the emergency rule.

Comment 4: The Advisory Panel should have been consulted on the emergency rule.

Response: NMFS makes every effort to consult the Advisory Panel prior to issuing FMP amendments or major and/or controversial rules. As described above, the Advisory Panel did provide comments during the comment period on the emergency rule. Additionally, NMFS is in the process of developing Amendment 1 to the HMS FMP that will take into consideration the comments and opinions of the Advisory Panel, stakeholders, conservationists and the public.

Comment 5: NMFS should report which states are allowing shark landings after federal closures and the magnitude of these landings for each state.

Response: NMFS provided a summary of this information at the Advisory Panel meeting and plans to make it available in Amendment 1 to the HMS FMP.

Comment 6: NMFS should implement minimum size limits for recreational fishermen.

Response: NMFS currently has a minimum size limit for recreational shark fishermen. Except for Atlantic sharpnose, recreational fishermen are authorized to keep one shark per vessel per trip larger than 4.5 feet fork length. There is no minimum size for Atlantic sharpnose sharks. NMFS may consider other minimum size requirements for recreational fishermen in Amendment 1 to the HMS FMP.

Comment 7: Based on the improved stock picture provided by the 2002 SCS assessment, NMFS should consider increasing the recreational bag and size limits for SCS. Recreational fishermen have been unfairly penalized by LCS and SCS assessments in the past.

Response: NMFS is examining several options for recreational fishing as part of Amendment 1 to the HMS FMP. NMFS may consider this option at that time.

Comment 8: Vessel upgrading restrictions are a safety concern. The current management regime forces smaller boats to fish further offshore in adverse conditions.

Response: Vessel upgrading restrictions were implemented to control excess fishing capacity in the shark fishery. NMFS believes that announcing the duration of the shark fishing season ahead of time should allow fishermen to avoid fishing under adverse conditions. NMFS is considering an amendment to some of the limited access regulations and will consider this issue in that process.

Comment 9: NMFS should leave a quota for incidental catch.

Response: NMFS is considering several quota alternatives in Amendment 1 to the HMS FMP and may consider this comment in that or in another rulemaking.

Comment 10: Harvesting sharks for meat or cartilage is completely unnecessary.

Response: NMFS disagrees. Sharks are a fishery resource that contributes to the food supply, economy, and health of the Nation as described in the Magnuson-Stevens Act.

Comment 11: NMFS should educate the public about sharks and their behavior to dispel the ''Jaws'' misconception. Sharks are much more economically valuable alive than dead.

Response: NMFS agrees that there are misconceptions about sharks and has made efforts to educate the public through various media including the internet. For instance, in early 2002, NMFS announced the availability of a website devoted exclusively to shark education at *http://www.nmfs.noaa.gov/sharks/* and will soon release an identification guide for all HMS including sharks. NMFS agrees that sharks are economically valuable, both as a harvested resource, and as an component of the marine environment that user groups, such as scuba divers, may wish to observe in the wild. NMFS believes that the sustainable harvest of sharks will not prevent segments of the population who derive economic benefit from sharks living in the wild or in public display facilities to continue doing so.

Comment 12: Sharks are top predators in the marine food chain and harvesting them will disrupt the food web.

Response: NMFS agrees that sharks are an important component of the marine environment and current regulations are designed to promote a sustainable fishery. Through sound conservation and management, NMFS believes that shark populations can be rebuilt and that the ocean's food web will not be disrupted.

Comment 13: NMFS should lobby Asians to stop shark finning.

Response: NMFS cannot regulate fishing vessels from other countries. However, the Shark Finning Prohibition Act which was passed on December 21, 2000, and implemented on February 2, 2002 (67 FR 6194), prevents any person subject to U.S. jurisdiction from engaging in shark finning (finning is the practice of removing the fin or fins from a shark and discarding the remainder of the shark). Additionally, the Shark Finning Prohibition Act requires the United States to initiate discussions with other nations regarding the prohibition on shark finning. NMFS has been working with other countries in regard to this. By becoming a signatory nation to the United Nations Food and Agriculture Organization's International Plan of Action on Sharks, the United States has agreed that shark conservation is a concern, both domestically and internationally. The United States has also agreed that all nations and international fishery organizations should take action to ensure that shark populations are monitored, and fishery conservation measures are implemented, to protect sharks from over-exploitation.

Comment 14: Sharks are going extinct.

Response: While some sharks species are overfished, NMFS does not believe they are going extinct. To the contrary, the most recent LCS and SCS stock assessments indicate that several of the most heavily exploited species are no longer overfished and that others are showing positive signs of recovery. Species that are of particular concern are on the candidate species list for listing under ESA, or are on the prohibited species list. However, no species are listed under the ESA at this time.

Comment 15: Sharks may be an important cure for cancer.

Response: NMFS agrees that sharks may be important in our search for cures to certain diseases, and NMFS fully supports further research in this area.

Clarification of the Dead Discard Accounting

After receiving public comments on the emergency rule issued December 27, 2002 (67 FR 78990), NMFS noted some confusion regarding which dead discards are counted against the commercial shark quotas. This confusion presented itself particularly in regard to SCS. Specifically, shrimp trawl discards of SCS from 1998 to 2000 ranged from 570 mt dw to 1,093 mt dw annually with an average of 744 mt dw of discards annually. This average amount is 418 mt dw greater than the SCS annual quota of 326 mt dw established by the emergency rule. As analyzed in the HMS FMP, the provision to count dead discards against the annual quota applies only to incidental catch by fishermen that hold HMS fishing permits.

Annual Landings Quotas

The 2003 annual landings quotas for LCS and SCS are maintained at 783 metric tons mt dw for ridgeback LCS, 931 mt dw for non-ridgeback LCS, and 326 mt dw for SCS. The 2003 quota levels for pelagic, blue, and porbeagle sharks are maintained at 488 mt dw, 273 mt dw, and 92 mt dw, respectively.

Of the 655.5 mt dw established for the second 2002 semiannual LCS season (67 FR 37354, May 29, 2002), 589 mt dw was taken. As explained in the notice announcing the first 2003 semiannual season (67 FR 78990, December 27, 2002), NMFS is adding the remaining 65 mt dw to the available quota for the second 2003 semiannual LCS fishing season. In the past, landings between the ridgeback and non-ridgeback LCS species groups have been approximately the same. Thus, this additional amount will be split equally between the ridgeback and non-ridgeback LCS species groups. As such, the ridgeback LCS quota for the second 2003 semiannual season is 424 mt dw. The non-ridgeback LCS quota for the second 2003 semiannual season is 498 mt dw. The SCS second 2003 semiannual quota is established at 163 mt dw. The second 2003 semiannual quotas for pelagic, blue, and porbeagle sharks are established at 244 mt dw, 136.5 mt dw, and 46 mt dw, respectively.

Fishing Season Notification

The second semiannual fishing season of the 2003 fishing year for the commercial fishery for ridgeback and non-ridgeback LCS, SCS, and pelagic sharks in the western north Atlantic Ocean, including the Gulf of Mexico and the Caribbean Sea, will open July 1, 2003. To estimate the closure dates of LCS, NMFS used the average catch rates for each species group from the second seasons from the years 2000, 2001, and 2002 and also considered the reporting dates of permitted shark dealers and the potential for discards. Based on average ridgeback LCS catch rates in recent years, approximately 75 percent of the available ridgeback LCS quota would likely be taken by the second week of September and approximately 90 percent of the available ridgeback LCS quota would likely be taken by the last week of September. Based on average non-ridgeback catch rates in recent years, approximately 80 percent on the non-ridgeback LCS quota would likely be taken by the second week in September and approximately 95 percent of the non-ridgeback LCS quota would likely be taken by the last week in September. The second week corresponds with the end of the first biweekly reporting period for September for permitted shark dealers. In order to ensure the quota is not exceeded once dead discards and state landings are accounted for, NOAA Fisheries believes closing the fishery by the second week of September is prudent. Accordingly, the Assistant Administrator for Fisheries (AA) has determined that the ridgeback and non-ridgeback LCS

quotas for the second 2003 semiannual season will likely be attained by September 15, 2003. Thus, the ridgeback and non-ridgeback LCS fisheries will close September 15, 2003, at 11:30 p.m. local time.

When quotas are projected to be reached for the SCS, pelagic, blue, or porbeagle shark fisheries, the AA will file notification of closure at the Office of the **Federal Register** at least 14 days before the effective date.

During a closure, retention of, fishing for, possessing or selling LCS are prohibited for persons fishing aboard vessels issued a limited access permit under 50 CFR 635.4. The sale, purchase, trade, or barter of carcasses and/or fins of LCS harvested by a person aboard a vessel that has been issued a permit under 50 CFR 635.4 are prohibited, except for those that were harvested, offloaded, and sold, traded, or bartered prior to the closure and were held in storage by a dealer or processor.

Classification

This emergency rule extension is published under the authority of the Magnuson-Stevens Act. The AA has determined that these emergency regulations are necessary to ensure that regulations in force are consistent with the best available science and a court-approved settlement agreement.

NMFS prepared an EA for the initial emergency rule that describes the impact on the human environment and found that no significant impact on the human environment would result. During the public comment period, NMFS became aware that several corrections and clarifications were needed for the initial EA. As a result, NMFS prepared a supplemental EA. None of the corrections or clarifications changed the findings of the EA or NMFS' decision to extend the emergency rule. Thus, the supplemental EA found that no significant impact on the human environment would result from extending the emergency rule. This emergency rule extension is of limited duration. Additional details concerning the basis for this action are contained in the initial emergency rule and are not repeated here. NMFS intends to have management measures in Amendment 1 to the HMS FMP in place by January 1, 2004.

NMFS also prepared a RIR for the emergency rule which assesses the economic costs and benefits of the action. Additional details concerning the basis for this action are contained in the initial emergency rule and are not repeated here.

This emergency rule extension to establish the 2003 landings quotas and other shark management actions has been determined to be not significant for the purposes of Executive Order 12866.

Additionally, the ancillary action announcing the fishing season is taken under 50 CFR 635.27(b) and is exempt from review under Executive Order 12866.

Because no general notice of proposed rulemaking is required to be published in the **Federal Register** for this emergency rule extension by 5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act do not apply; thus, no Regulatory Flexibility Analysis was prepared.

Pursuant to provisions of 15 CFR part 930 and Section 307 of the Coastal Zone Management Act of 1972, state Coastal Zone Management (CZM) Programs, including Puerto Rico and the U.S. Virgin Islands, were advised of NMFS' determination that the emergency rule was consistent with the enforceable provisions of the CZM Programs. Of the eleven responses received, all concurred with NMFS' determination.

The AA finds that it is unnecessary and contrary to the public interest to provide prior notice of and an opportunity for public comment on this emergency rule extension. In the initial emergency rule published on December 27, 2002 (67 FR 78990), NMFS requested, and subsequently received, comments on these management measures. Therefore, the agency has the authority to extend the emergency rule for another 180 days.

This emergency rule extension contains the same measures as in the initial emergency rule and must be in place by July 1, 2003, otherwise LCS quotas and certain other management measures from the 1999 HMS FMP, which were based on the 1998 LCS stock assessment, will go into effect. After reviewing the independent peer reviews of the 1998 assessment, which were required as part of a court-approved settlement agreement, NMFS determined that portions of the 1998 assessment did not constitute the best available science. Allowing the LCS quotas from the 1999 FMP to go into effect, thus, would be inconsistent with National Standard 2 of the Magnuson-Stevens Act and also would result in a significant adverse economic impact to LCS fishermen, as fishing quotas that have been at least 1,285 mt dw for LCS since 1997 would be reduced by at least 36 percent. Additionally, the settlement agreement contemplated that NMFS would not adjust LCS quotas and other management measures in the 1999 HMS FMP until after a peer review process on a new LCS stock assessment was complete, but could take emergency action as needed pending completion of the review process.

Since publication of the initial emergency rule, NMFS has held four public hearings and solicited comment on the rule during a 50 day comment period, reviewed and analyzed the findings of the peer reviews of the 2002 LCS stock assessment, and continued to work on Amendment 1 to the HMS FMP to address long-term, comprehensive shark management measures based on the 2002 LCS and SCS stock assessments. NMFS also developed an issues and options paper for Amendment 1 to the HMS FMP, and held seven scoping meetings including one at the February 2003 meeting of the HMS and Billfish Advisory Panels. NMFS has received extensive public comment on the emergency rule as a result of these processes, and as noted above, this extension would not change any measures from the initial emergency rule.

NMFS will consider many of the comments received on this action in the course of developing Amendment 1 to the HMS FMP. Therefore, for all of the above reasons, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment.

Dated: May 22, 2003.

Rebecca J. Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 03–13420 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 030314060–3126-02; I.D. 021003E]

RIN 0648-AQ57

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid and Butterfish Fisheries; Framework Adjustment 3

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement measures contained in Framework Adjustment 3 (Framework 3) to the Atlantic Mackerel, Squid, and

Butterfish Fishery Management Plan (FMP). This action extends the limited entry program for the Illex squid fishery for an additional year and is intended to further the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Effective June 30, 2003.

ADDRESSES: Copies of Framework 3, including the Environmental Assessment (EA), Regulatory Impact Review (RIR) and Final Regulatory Flexibility Analysis (FRFA) are available upon request from Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council, 300 South New Street, Dover, DE 19904–6790. The EA/RIR/FRFA is accessible via the Internet at *http://www.nero.noaa.gov/ro/doc/com.htm*.

FOR FURTHER INFORMATION CONTACT: Paul H. Jones, Fishery Policy Analyst, 978–281-9273, fax 978–281-9135, e-mail Paul.H.Jones@noaa.gov.

SUPPLEMENTARY INFORMATION: In 1997, Amendment 5 to the FMP established a limited entry program for the *Illex* squid fishery in response to a concern that fishing capacity could otherwise expand to overexploit the stock. At the time the program was established, there was a concern that the capacity of the limited entry vessels might prove, over time, to be insufficient to fully exploit the annual quota. In response to this concern, a 5-year sunset provision was placed on the *Illex* squid limited entry program. Framework 2 to the FMP extended the *Illex* squid moratorium for 1 year, and it is currently scheduled to end on July 1, 2003. Since the implementation of the limited entry program, the *Illex* squid fishery's performance has demonstrated that the current fleet possesses the capacity to harvest the long-term potential yield from this fishery. The Mid-Atlantic Fishery Management Council (Council) must prepare an amendment to the FMP (Amendment 9) to evaluate whether or not the limited entry program should be made permanent. In the meantime, this action extends the *Illex* squid moratorium through July 1, 2004, to prevent overcapitalization while Amendment 9 is being prepared and considered by the Council. This extension would comply with the criteria in section 303(b)(6) of the Magnuson-Stevens Act. The extension would allow the Council additional time to consider long-term management for the *Illex* squid fishery, including the limited entry program. Vessels that took small quantities of *Illex* squid in the past may continue to do so under the incidental catch provision of the FMP.

Comments and Responses

The Council developed Framework 3 under the framework abbreviated rulemaking procedure codified at 50 CFR part 648, subpart B. This procedure provided the public with the opportunity to comment on the proposed actions at Council meetings held in October and December 2002. In addition, the proposed rule provided an opportunity for public comment. Two commenters submitted one comment on the proposed rule.

Comment: The commenters supported extending the Illex squid moratorium through July 1, 2004, while Amendment 9 is being prepared and considered by the Council.

Response: This final rule implements the proposed measure.

There were no changes from the proposed rule.

Classification

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Council and NMFS prepared a FRFA for this action. Two comments were submitted on the proposed rule, but were not specific to the initial regulatory flexibility analysis (IRFA) or economic impacts of the rule. No changes were made to the proposed rule as a result of the comments received. This action does not contain any reporting, or recordkeeping requirements. There are 73 vessels that have been issued moratorium permits, all of which would be impacted by this action. Since the data are not available to calculate per vessel costs for vessels participating in the *Illex* moratorium fishery, individual vessel profitability could not be estimated. Therefore, changes in gross revenue of the aggregate fleet is used as a proxy for changes in individual vessel profitability. Furthermore, assumptions are made that revenue losses and gains are shared equally among all vessels. NMFS' guidelines suggest consideration of disproportionate economic impacts between large and small entities that may result from the regulatory action. Because there are no large entities (vessels) participating in this fishery, small vessels will not be placed at a competitive disadvantage relative to large vessels, thus rendering the issue of disproportionate impacts between these two classes moot. The FRFA consists of the IRFA and a summary of the analyses done in support of this action. A copy of the analyses is available from the Council (see **ADDRESSES**) or via the Internet at *http://www.nero.noaa.gov/ro/doc/com.htm*. A summary of the FRFA follows:

In addition to the preferred Alternative 1, the Council considered three non-preferred alternatives. Alternative 2 would extend the moratorium on entry to the *Illex* fishery for an additional 2 years (through July 1, 2005); Alternative 3 would extend the moratorium on entry to the *Illex* fishery for an additional 3 years (through July 1, 2006); and Alternative 4 would allow the moratorium on entry to the *Illex* fishery to expire on July 1, 2003 (no action).

The preferred alternative and Alternatives 2 and 3 would extend the moratorium on entry of new vessels into the *Illex* fishery; therefore, no impact is expected on vessels in the fishery in 2003 (and the first half of 2004), compared to individual vessel revenues in 2002. The Council assumed that the market and prices would remain stable. Therefore, any changes in individual vessel revenues would be the result of factors outside the scope of the moratorium (e.g., change in fishing practices for individual vessels, or changes in abundance and distribution of *Illex* squid).

Under Alternative 4, the no-action alternative, the *Illex* fishery would revert to open access. This would result in an increase in fishing effort in the *Illex* fishery. New vessels entering the fishery would limit per vessel share of the *Illex* squid quota and reduce revenues for the present participants. Computing the total revenue losses for the existing moratorium vessels is impossible due to the unpredictability of redirection of effort into the *Illex* squid fishery. Therefore, the Council developed a sensitivity analysis to determine the impact of the entry of additional vessels into the fishery on revenues earned by individual vessels already engaged in the fishery. The sensitivity analysis examined three scenarios that presumed revenues derived from landings of *Illex* squid would be reduced by 75, 50, and 25 percent. The analysis was based on 1998 data because in 1998 the *Illex* quota was completely harvested. Therefore, those data would allow the greatest impact to be assessed.

Under scenario 1, the review of revenue impacts examined the landings of vessels that landed at least 1 pound (0.45 kg) of *Illex* in 1998 and presumed that revenues derived from landing *Illex* for these vessels would be reduced by 75 percent. The 109 impacted vessels (the 73 vessels with moratorium permits, plus open access vessels who landed *Illex* in 1998) were projected to be impacted by revenue losses that ranged from less than 5 percent for 79 vessels, to a maximum of 40–49 percent

for two vessels. There were no impacted vessels home-ported in Maryland, New Hampshire, or Virginia; a high of 15 vessels had home ports in New Jersey. Other impacted vessels were home-ported in Massachusetts, Maine, Rhode Island, New York, and North Carolina. Presumably, other vessels entering the fishery would experience gains in revenues.

Under scenario 2, the review of revenue impacts presumed that vessel revenues derived from landing *Illex* would be reduced by 50 percent. The 109 impacted vessels were projected to be impacted by revenue losses that ranged from less than 5 percent for 84 vessels, to a maximum of 30–39 percent for one vessel. There were no impacted vessels home-ported in Maryland, New Hampshire, or Virginia; a high of 11 vessels had home ports in New Jersey. Others were in Massachusetts, Maine, Rhode Island, and North Carolina. Presumably, other vessels entering the fishery would experience gains in revenues.

Under scenario 3, the review of revenue impacts presumed that vessel revenues derived from landing *Illex* would be reduced by 25 percent. The 109 impacted vessels were projected to be impacted by revenue losses that ranged from less than 5 percent, for 88 vessels, to a maximum of 10–19 percent for eight vessels. The number of impacted vessels by home state ranged from none in Maryland, New Hampshire, New York, and Virginia, to a high of 11 in New Jersey. Other impacted vessels were home-ported in Massachusetts, Maine, Rhode Island, and North Carolina.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: May 23, 2003.

Rebecca Lent,

Deputy Assistant Administrator for Regulatory programs, National Marine Fisheries Service.

■ For the reasons set out in the preamble, 50 CFR part 648 is amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.4, the heading of paragraph (a)(5)(i) is revised to read as follows:

§ 648.4 Vessel permits.

(a) * * *

(5) * * *

(i) *Loligo squid/butterfish and Illex squid moratorium permits (Illex squid moratorium is applicable from July 1, 1997, until July 1, 2004).* * * *

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[FR Doc. 03–13419 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 68, No. 103
Thursday, May 29, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–187–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330 and A340 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Airbus Model A330 and A340 series airplanes. This proposal would require, among other actions, a detailed inspection of the rudder travel limitation unit for proper adjustment, measurement of the desynchronization of rudder servo-controls, installation of rigging placards for rudder servo-controls, and follow-on and corrective actions, if necessary. This action is necessary to prevent desynchronization of the rudder servo-controls, which could result in high load factors on the rudder servo-controls, and consequent reduced structural integrity of the attachment fittings for the rudder servo-controls. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by June 30, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–187–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–187–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–187–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–187–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on all Airbus Model A330 and A340 series airplanes. The DGAC advises that it has received several reports of abnormal stiff application of the rudder pedal in flight and during ground tests. Investigation revealed cracks on the attachment fittings for the blue rudder servo-controls and on the spherical bearing of the tail lock for the blue rudder servo-controls. Also, the actuating spring rod of the blue rudder servo-controls was found to be shorter than the actuating spring rods of the yellow and green rudder servo-controls, which resulted in desynchronization of the rudder servo-controls. The high load factors induced by the desynchronization caused the cracks on the attachment fittings for the servo-controls and spherical bearing. The desynchronization was caused by deviation from the procedures for adjusting actuating spring rods of the rudder servo-controls. This condition, if not corrected, could result in high load factors on the rudder servo-controls, and consequent reduced structural integrity of the attachment fittings for the rudder servo-controls.

Explanation of Relevant Service Information

Airbus has issued Service Bulletin A330–27–3084 (for Model A330 series airplanes); and Service Bulletin A340–27–4088 (for Model A340 series airplanes); both dated March 28, 2001. These service bulletins describe

procedures for performing a detailed inspection of the rudder travel limitation unit (RTLU) for proper adjustment, and measuring desynchronization of the rudder servo-controls. The inspection of the RTLU includes installing rigging pins on the bellcrank and right and left input levers and, if necessary, adjusting the length of the applicable adjustable rod. Measurement of the rudder servo-controls for desynchronization includes disconnecting the control rod from the bellcrank; installing a rigging pin on the bellcrank assembly of the lower servo-controls; pressurizing and depressurizing the blue, yellow, and green hydraulic systems at the appropriate times; recording the results; if desynchronization is found, determining if the value is within the acceptable limits specified in the service bulletins; replacing or adjusting the actuating spring rods and affected rudder servo-controls; and returning replaced rudder servo-controls with the highest load factors to the manufacturer; as applicable.

For airplanes on which any rudder servo-control has been replaced per Service Bulletin A330–27–3084 or Service Bulletin A340–27–4088, Airbus has also issued Service Bulletin A330–55–3028 (for Model A330 series airplanes); and Service Bulletin A340–55–4026 (for Model A340 series airplanes); including Appendix 01; dated May 28, 2001. These service bulletins describe procedures for a detailed or high frequency eddy current inspection of the attachment fittings of desynchronized rudder servo-controls for cracks. The service bulletins describe procedures for follow-on actions (including additional detailed inspections in the area of the fasteners and attachment fittings; additional high frequency eddy current inspections; cold expansion of specific fastener holes; drilling/reaming and cleaning of specific fastener holes; rotating probe inspections; and wet installation of pins, collars, and oversize fasteners) depending on airplane configuration; as applicable; and repetitive inspections. The service bulletins also state that if any crack is found, operators should contact Airbus for repair instructions.

For certain Model A330 series airplanes, Airbus Service Bulletin A330–27–3084 recommends concurrent accomplishment of Airbus Service Bulletin A330–27–3082, dated March 28, 2001. Service Bulletin A330–27–3082 describes procedures for installing rigging placards for the rudder servo-controls (including bonding placards to the appropriate areas and coating them with lacquer).

For certain Model A340 series airplanes, Airbus Service Bulletin A340–27–4088 recommends concurrent accomplishment of Airbus Service Bulletin A340–27–4086, dated March 28, 2001. Service Bulletin A340–27–4086 describes procedures for installing rigging placards for the rudder servo-controls (including bonding placards to the appropriate areas and coating them with lacquer).

Accomplishment of the actions specified in these service bulletins is intended to adequately address the identified unsafe condition. The DGAC classified these service bulletins as mandatory and issued French airworthiness directives 2001–156(B) and 2001–157(B), both dated May 2, 2001, in order to assure the continued airworthiness of these airplanes in France.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the applicable service bulletins described previously, except as discussed below.

Differences Between Foreign Airworthiness Directives, Service Bulletins, and Proposed AD

Operators should note that although French airworthiness directives 2001–156(B) and 2001–157(B); and Airbus Service Bulletins A330–55–3028 (for Model A330 series airplanes) and A340–55–4026 (for Model A340 series airplanes); include instructions for reporting inspection results and returning desynchronized rudder servo-controls with the highest load factors to Airbus, this proposed AD would not require those actions.

Operators should also note that, although Airbus Service Bulletins A330–55–3028 and A340–55–4026 specify that the manufacturer may be contacted for certain repair instructions, this proposal would require the repair be accomplished in accordance with a method approved by either the FAA, or the DGAC (or its delegated agent). In light of the type of repair that would be required to address the identified unsafe condition, and in consonance with existing bilateral airworthiness agreements, the FAA has determined that, for this proposed AD, a repair approved by either the FAA or the DGAC (or its delegated agent) would be acceptable for compliance with this proposed AD.

Cost Impact

The FAA estimates that 9 Model A330 series airplanes of U.S. registry would be affected by this proposed AD, that it would take 6 work hours per airplane to accomplish the proposed inspection and measurement, and 1 work hour per airplane to accomplish the proposed installation of the rigging placards, and that the average labor rate is $60 per work hour. Required rigging placards would be provided to the operators at no cost. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $3,780, or $420 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Currently, there are no Airbus Model A340 series airplanes on the U.S. Register. However, should an affected airplane be imported and placed on the U.S. Register in the future, it would require 6 work hours per airplane to accomplish the proposed inspection and measurement, and 1 work hour per airplane to accomplish the proposed installation of the rigging placards, at an average labor rate of $60 per work hour. Required placards would be provided to the operators at no cost. Based on these figures, the cost impact of the proposed AD for Model A340 operators would be $420 per airplane.

Regulatory Impact

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

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Airbus: Docket 2001–NM–187–AD.

Applicability: Model A330 and A340 series airplanes, certificated in any category; except those airplanes modified in production in accordance with Airbus Modification 48110.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent desynchronization of the rudder servo-controls, which could result in high load factors on the rudder servo-controls, and consequent reduced structural integrity of the attachment fittings for the rudder servo-controls, accomplish the following:

Inspection of Rudder Travel Limitation Unit

(a) Within 16 months after the effective date of this AD: Perform a one-time detailed inspection of the rudder travel limitation unit (RTLU) (including installing rigging pins on the bellcrank and the right and left input levers) for proper adjustment, per the Accomplishment Instructions specified in Airbus Service Bulletin A330–27–3084 (for Model A330 series airplanes); or Airbus Service Bulletin A340–27–4088 (for Model A340 series airplanes); both dated March 28, 2001; as applicable. Although the service bulletins reference a reporting requirement, such reporting is not required by this AD.

(1) If it is possible to install rigging pins on both input levers, the RTLU is properly adjusted and no further action is required by this paragraph.

(2) If it is not possible to install the rigging pins on either input lever, before further flight, adjust the length of the appropriate adjustable rod, per the Accomplishment Instructions specified in the applicable service bulletin.

Note 2: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Measurement of Rudder Servo-Controls Desynchronization and Corrective Action if Necessary

(b) Within 16 months after the effective date of this AD: Measure the desynchronization value (value D) of the rudder servo-controls and, depending on the measurement, before further flight, perform the applicable corrective actions (e.g., replacement and/or adjustment of the spring rod and/or the rudder servo-controls); per the Accomplishment Instructions specified in Airbus Service Bulletin A330–27–3084 (for Model A330 series airplanes); or Airbus Service Bulletin A340–27–4088 (for Model A340 series airplanes); both dated March 28, 2001; as applicable. Operators should note that although these service bulletins request that desynchronized rudder servo-controls with the highest load factors be returned to the manufacturer, that action is not required by this AD.

(c) If any rudder servo-control was replaced per the requirements of paragraph (b) of this AD, do paragraphs (c)(1) and (c)(2) of this AD.

(1) Before further flight, perform either a detailed inspection or a high frequency eddy current (HFEC) inspection for cracks in the attachment fittings of the desynchronized rudder servo-controls, and perform the applicable follow-on and corrective actions (e.g., cold expansion of affected fastener holes, drilling/reaming of affected holes, and rotating probe inspections), per the Accomplishment Instructions specified in Airbus Service Bulletin A330–55–3028 (for Model A330 series airplanes); or Airbus Service Bulletin A340–55–4026 (for Model A340 series airplanes); excluding Appendix 01; dated May 28, 2001; as applicable; except where the service bulletin specifies to contact the manufacturer for repair instructions, repair per a method approved by the Manager, International Branch, ANM–116, FAA.

(2) Repeat the inspection required by paragraph (c)(1) of this AD at the following intervals:

(i) If the immediately preceding inspection was conducted using detailed inspection techniques, conduct the next inspection within 300 flight cycles; or

(ii) If the immediately preceding inspection was conducted using HFEC techniques, conduct the next inspection within 6,000 flight cycles.

Concurrent Requirements

(d) Concurrently with the requirements of paragraphs (a) and (b) of this AD, install appropriate rigging placards for the rudder servo-controls, per Airbus Service Bulletin A330–27–3082 (for Model A330 series airplanes); or Airbus Service Bulletin A340–27–4086 (for Model A340 series airplanes); both dated March 28, 2001; as applicable.

Alternative Methods of Compliance

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in French airworthiness directives 2001–156(B) and 2001–157(B), both dated May 2, 2001.

Issued in Renton, Washington, on May 21, 2003.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13389 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–27–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747 Series Airplanes Equipped With Pratt & Whitney JT9D–3 or JT9D–7 Series Engines (Except JT9D–70 Series Engines)

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to Boeing Model 747 series airplanes equipped with Pratt & Whitney JT9D–3 or JT9D–7 series engines (except JT9D–70 series engines). This proposal would require detailed inspections of the upper and lower surface of the forward lower spar of the nacelle strut for cracking or other damage, and for any loose or damaged fasteners. This proposal would also require replacement of loose or damaged fasteners and, if necessary, associated repair of the forward lower spar. This action is necessary to detect and correct cracking or other damage to the upper or lower surface of the forward lower spar and any loose or damaged fasteners, which could result in reduced structural capability of nacelle struts one through four, and possible separation of a strut and engine from the airplane during flight. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by July 14, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–27–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2002–NM–27–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Tamara Anderson, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6421; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2002–NM–27–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–27–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports of multiple loose and damaged fasteners and lower spar web damage of the No. 4 strut on two Boeing Model 747 series airplanes equipped with Pratt & Whitney JT9D–7 engines. This damage was observed at approximately 1,900 and 2,900 flight cycles after incorporation of the strut modification described in Boeing Alert Service Bulletin 747–54A2159, dated November 3, 1994. That modification was made mandatory by AD 95–10–16, amendment 39–9233 (60 FR 27008, May 22, 1995). Analysis by Boeing indicates that the loose fasteners were the result of incorrect installation of the fasteners or the collars. Multiple loose fasteners allow out-of-plane web deflection and damage to the lower spar web and fasteners. The resulting damage could cause cracking and the loss of the lower spar. This condition, if not corrected, could result in reduced structural capability of the strut, and possible separation of the strut and engine from the airplane during flight.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001, including Evaluation Form, which describes procedures for the following actions:

Part 1: A detailed inspection of (a) the upper surface of the forward lower spar for cracking and fretting damage to the web, forward bulkhead channel, and stiffeners; and (b) the fasteners in that area for missing heads, damage, and evidence of looseness, such as cracked or broken sealant and fretting or galling around the collars, nuts, or fastener heads.

Part 2: A detailed inspection of (a) the lower surface of the forward lower spar for cracking and fretting damage to the web, c-channel, chords, and stiffener; and (b) the fasteners in that area for missing heads, damage, and evidence of

looseness, such as cracked or broken sealant and fretting or galling around the collars, nuts, or fastener heads.

Part 3: Corrective action, which includes removing loose or damaged fasteners, examining the fastener holes for damage or cracks using a high frequency eddy current (HFEC) inspection, removing cracks or damage by oversizing the holes, ensuring that all cracks and damage are removed using a follow-up HFEC inspection, reaming the hole to a minimum size, and installing a new fastener.

Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001, also specifies that, if damage or cracking is found which cannot be removed by oversizing a hole per the alert service bulletin, the Boeing Company should be contacted for additional instructions.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the alert service bulletin described previously, except as discussed below.

Differences Between Alert Service Bulletin and Proposed AD

Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001, specifies that the manufacturer is to be contacted for disposition of damage or cracks which cannot be repaired by oversizing a fastener hole per the alert service bulletin. The proposed AD, however, would require such repair to be accomplished per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make such findings.

Another difference involves inspection of the upper surface and the lower surface of the forward lower spar. The alert service bulletin recommends inspection of the upper surface after accumulation of 300 flight cycles since modification of the strut in accordance with AD 95–10–16. Inspection of the lower surface is to be done after accumulation of 1,300 flight cycles since modification. This proposed AD, however, provides that, for airplanes which have accumulated 1,300 or more flight cycles since modification of the strut, the initial inspection may include both the upper surface and the lower surface of the forward lower spar. If no damage is detected, no further action is required by the AD.

Cost Impact

There are approximately 366 airplanes of the affected design in the worldwide fleet. The FAA estimates that 115 airplanes of U.S. registry would be affected by this proposed AD, that it would take from 20 to 64 work hours per airplane to accomplish the proposed inspections, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed inspections is estimated to be between $1,200 and $3,840 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 2002–NM–27–AD.

Applicability: Model 747 series airplanes, equipped with Pratt & Whitney JT9D–3 or JT9D–7 series engines (excluding JT9D–70 series engines), as listed in Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001; certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To detect and correct cracking or other damage to the structure of the upper or lower surface of the forward lower spar and any loose or damaged fasteners, which could result in reduced structural capability of nacelle struts one through four, and possible separation of the strut and engine from the airplane during flight, accomplish the following:

Inspection of Upper Surface of Forward Lower Spar

(a) At the later of the times shown in paragraphs (a)(1) and (a)(2) of this AD: Perform a detailed inspection of the upper surface of the forward lower spar to detect cracks, fretting damage, and any loose or damaged fasteners, in accordance with Part 1 of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001, excluding Evaluation Form.

(1) Within 500 flight cycles, but no sooner than 300 flight cycles, after modification of the strut in accordance with AD 95–10–16, amendment 39–2933.

(2) Within 6 months after the effective date of this AD; or

Note 2: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Inspection of Lower Surface of Forward Lower Spar

(b) If the detailed inspection required by paragraph (a) of this AD reveals any crack or fretting damage, or any loose or damaged fastener: Prior to further flight, perform a detailed inspection of the lower surface of the forward lower spar to detect cracks, fretting damage, and any loose or damaged fasteners, in accordance with Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001, excluding Evaluation Form.

Follow-up Inspection

(c) If the detailed inspection of the upper surface of the forward lower spar required by paragraph (a) of this AD reveals no crack or fretting damage and no loose or damaged fastener: At the later of the times specified in paragraphs (c)(1) and (c)(2) of this AD, repeat the detailed inspection of the upper surface of the forward lower spar and perform a detailed inspection of the lower surface of the forward lower spar, in accordance with Parts 1 and 2, respectively, of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001, excluding Evaluation Form.

(1) Within 1,500 flight cycles, but no sooner than 1,300 flight cycles, after modification of the strut, in accordance with AD 95–10–16; or

(2) Within 18 months after the effective date of this AD.

Optional Follow-Up Inspection

(d) If the detailed inspection of the upper surface of the forward lower spar required by paragraph (a) of this AD reveals no crack or fretting damage, and no loose or damaged fastener: Prior to further flight, the operator may elect to perform a detailed inspection of the lower surface of the forward lower spar to detect cracks, fretting damage, and any loose or damaged fasteners, in accordance with Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001, excluding Evaluation Form, provided that the airplane has accumulated at least 1,300 flight cycles since modification of the strut per AD 95–10–16.

Corrective Action

(e) If any detailed inspection described in paragraph (a), (b), (c), or (d) of this AD reveals any crack or fretting damage to the upper or lower surface of the forward lower spar or any loose or damaged fastener: Prior to further flight, accomplish the actions specified in paragraph (e)(1) or (e)(2) of this AD, as applicable.

(1) If the crack or fretting damage to the upper or lower surface of the forward lower spar falls within the parameters specified in Figure 4 or 5 (as applicable) of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001, excluding Evaluation Form, and the airplane has accumulated 1,300 flight cycles or more since modification of the strut per AD 95–10–16: Remove any loose or damaged fasteners, repair any cracks or fretting damage to the upper or lower surface of the forward lower spar, and install new fasteners, in accordance with the Accomplishment Instructions of the service bulletin. No further action is required by this AD.

(2) If the crack or fretting damage to the upper or lower surface of the forward lower spar does not fall within the parameters specified in Figure 4 or 5 (as applicable) of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2209, dated November 8, 2001, excluding Evaluation Form, or if the airplane has accumulated fewer than 1,300 flight cycles since modification of the strut per AD 95–10–16: Accomplish additional repair per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved as required by this paragraph, the approval must specifically reference this AD.

(f) If the detailed inspection specified in paragraph (c) or (d) of this AD reveals no cracks or other damage to the upper or lower surface of the forward lower spar and no loose or damaged fasteners, no further action is required by this AD.

Alternative Methods of Compliance

(g) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

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

Special Flight Permits

(h) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on May 22, 2003.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13388 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–314–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300 B4–600, B4–600R, and F4–600R (Collectively Called A300–600) Series Airplanes, and Airbus Model A310 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Airbus Model A300 B4–600, B4–600R, and F4–600R (collectively called A300–600) series airplanes, and Airbus Model A310 series airplanes. This proposal would require replacement of Honeywell inertial reference units (IRU) with new or modified Honeywell IRUs. For certain airplanes, this proposal also would require replacement of Litton IRUs, mode selector units (MSU), and inertial sensor display unit (ISDU) with new Honeywell IRUs, MSUs, and a new ISDU. This action is necessary to prevent loss of positioning data and a display of incorrect attitude data, which could compromise the ability of the flightcrew to maintain the safe flight and landing of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by June 30, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–314–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent

via fax or the Internet must contain ''Docket No. 2001–NM–314–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–314–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–314–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Airbus Model A300 B4–600, B4–600R, and F4–600R (collectively called A300–600) series airplanes, and Airbus Model A310 series airplanes, equipped with certain Honeywell Inertial Reference Units (IRU). The DGAC advises that an operator reported the loss of positioning data and the display of incorrect attitude data shortly after take-off because the airplane was moved on the ground before the IRU alignment procedure had been completed. This condition, if not corrected, could result in loss of positioning data and a display of incorrect attitude data, which could compromise the ability of the flightcrew to maintain the safe flight and landing of the airplane.

Explanation of Relevant Service Information

Airbus has issued Service Bulletin A300–34–6135, Revision 01 (for Model A300–600 series airplanes); and Service Bulletin A310–34–2158, Revision 01 (for Model A310 series airplanes); both dated September 10, 2001. These service bulletins describe procedures for replacement of Honeywell IRUs with new or modified Honeywell IRUs.

The service bulletins reference Honeywell Service Bulletin HG1050BD–34–0009, dated April 17, 2001; and Honeywell Service Bulletin HG1050BD–34–0010, Revision 001, dated April 16, 2001; as additional sources of service information for accomplishing the replacement of Honeywell IRUs required by this AD.

For certain Model A300–600 series airplanes, Airbus Service Bulletin A300–34–6135 recommends prior or concurrent accomplishment of Airbus Service Bulletin A300–34–6082, Revision 05, dated February 13, 1998. Service Bulletin A300–34–6082 describes procedures for replacing Litton IRUs, mode selector units (MSU), and inertial sensor display unit (ISDU) with new Honeywell IRUs, MSUs, and a new ISDU.

For a certain Model A310 series airplane, Airbus Service Bulletin A310–34–2158 recommends prior or concurrent accomplishment of Airbus Service Bulletin A310–34–2104, dated May 12, 1995. Service Bulletin A310–34–2104 describes procedures for replacing Litton IRUs, MSUs, and the ISDU unit with new Honeywell IRUs, MSUs, and a new ISDU.

Accomplishment of the actions specified in the Airbus service bulletins is intended to adequately address the identified unsafe condition. The DGAC classified the Airbus service bulletins as mandatory and issued French airworthiness directive 2001–303(B), dated July 25, 2001, in order to assure the continued airworthiness of these airplanes in France.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletins described previously.

Cost Impact

The FAA estimates that 89 Airbus Model A300–600 series airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 3 work hours per airplane to accomplish the proposed replacement of Honeywell IRUs with new or modified Honeywell IRUs, and that the average labor rate is $60 per work hour. Required parts would cost approximately $1,000 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $105,020, or $1,180 per airplane.

The FAA estimates that 47 Airbus Model A310 series airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 3 work hours per airplane to accomplish the proposed replacement of Honeywell IRUs with new or modified Honeywell IRUs, and that the average labor rate is $60 per work hour. Required parts would cost approximately $1,000 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $55,460, or $1,180 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Airbus: Docket 2001–NM–314–AD.

Applicability: The series airplanes, certificated in any category, listed in the following table:

TABLE—APPLICABILITY

Model—	Equipped with Honeywell ineritial reference units having part number—	Excluding airplanes modified in accordance with—
A300 B4–600, A300 B4–600R, and A300 F4–600R (collectively called A300–600); and A310.	HG1050BD02 or HG1050BD05	Airbus Modification 12304 in production; or Airbus Service Bulletin A300–34–6135, Revision 01, dated September 10, 2001 (for Model A300–600 series airplanes) or Airbus Service Bulletin A310–34–2158, Revision 01, dated September 10, 2001 (for Model A310 series airplanes); as applicable.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of positioning data and a display of incorrect attitude data to the flightcrew, which could compromise the ability of the flightcrew to maintain the safe flight and landing of the airplane, accomplish the following:

Replacement of Inertial Reference Units (IRU)

(a) Within 35 months after the effective date of this AD: Replace the existing Honeywell IRUs with new or modified Honeywell IRUs, per the Accomplishment Instructions specified in Airbus Service Bulletin A300–34–6135, Revision 01 (for Model A300 B4–600, A300 B4–600R, and A300 F4–600R (collectively called A300–600 series airplanes)); or Service Bulletin A310–34–2158, Revision 01 (for Model A310 series airplanes); both dated September 10, 2001; as applicable.

(b) Accomplishment of the replacement specified in Airbus Service Bulletin A300–34–6135 (for Model A300–600 series airplanes); or Service Bulletin A310–34–2158 (for Model A310 series airplanes); both dated March 9, 2001; as applicable; is acceptable for compliance with the replacement requirement of paragraph (a) of this AD.

Note 2: Airbus Service Bulletin A300–34–6135, Revision 01; and Airbus Service Bulletin A310–34–2158, Revision 01; both dated September 10, 2001; reference Honeywell Service Bulletin HG1050BD–34–0009, dated April 17, 2001; and Honeywell Service Bulletin HG1050BD–34–0010, Revision 001, dated April 16, 2001; as additional sources of service information for accomplishing the replacements required by this AD.

For Model A300–600 Series Airplanes: Before or Concurrent Requirements

(c) For Model A300–600 series airplanes with manufacturer's serial numbers 0284, 0294, 0301, 0307, 0312, 0317, 0321, 0336, 0341, 0348, 0351, 0555, 0559, 0625, 0677, 0743, 0744, and 0749: Before or concurrently with the requirements of paragraph (a) of this AD, replace the Litton IRUs, mode selector units (MSU), and inertial sensor display unit (ISDU) with new Honeywell IRUs, MSUs, and a new ISDU, per Airbus Service Bulletin A300–34–6082, Revision 05, dated February 13, 1998. If this service bulletin is being performed concurrently with the requirements of paragraph (a) of this AD, the new or modified Honeywell IRUs required by paragraph (a) of this AD should be installed in lieu of the Honeywell part numbers listed in Revision 05 of Airbus Service Bulletin A300–34–6082.

For Model A310 Series Airplanes: Before or Concurrent Requirements

(d) For the Model A310 airplane with manufacturer's serial number 0172: Before or concurrently with the requirements of paragraph (a) of this AD, replace the Litton IRUs, MSUs, and ISDU with new Honeywell IRUs, MSUs, and a new ISDU, per Airbus Service Bulletin A310–34–2104, dated May 12, 1995.

Parts Installation

(e) As of the effective date of this AD, no person shall install, on any airplane, any part listed in paragraphs (e)(1), (e)(2), or (e)(3) of this AD; as applicable:

(1) For Model A300–600 series airplanes and Model A310 series airplanes: Honeywell IRUs having part number HG1050BD02 or HG1050BD05.

(2) For Model A300–600 airplanes listed in paragraph (c) of this AD: Litton IRUs, MSUs, or ISDU having a part number identified in paragraph 3.A. of Airbus Service Bulletin A300–34–6082, Revision 5, dated February 13, 1998.

(3) For Model A310 airplane listed in paragraph (d) of this AD: Litton IRUs having part number 4618000200–2201 or 461800–02–102; MSUs having part number 461630–02; and an ISDU having part number 461640–08–03.

Alternative Methods of Compliance

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Avionics Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in French airworthiness directive 2001–303(B), dated July 25, 2001.

Issued in Renton, Washington, on May 22, 2003.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13387 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–13–AD]

RIN 2120–AA64

Airworthiness Directives; Learjet Model 45 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Learjet Model 45 airplanes, that currently requires repetitive application of grease to the rotating disk assembly of the nose landing gear (NLG) squat switch mechanism. This action would require replacement of the squat switch camrod of the NLG, which would terminate the repetitive application; and would also reduce the applicability of the exiting AD. This proposed AD is prompted by results of tests conducted by the airplane manufacturer. The actions specified by this proposed AD are intended to prevent moisture contamination and subsequent formation of ice which could cause bending and damage of the squat switch assembly, driving the nose wheel to an uncommanded angle against the force of the steering system. This condition, if not corrected, could result in the airplane departing the runway at high speeds during landing.

DATES: Comments must be received by July 14, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FDAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–13–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2002–NM–13–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Learjet, Inc., One Learjet Way, Wichita, Kansas 67209–2942. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Robert Busto, Aerospace Engineer, Systems and Equipment Branch, ACE–116W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946–4157; fax (316) 946–4107

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.,* reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Comments wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2002–NM–13–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate,

ANM–114, Attention: Rules Docket No. 2002–NM–13–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On October 23, 2000, the FAA issued AD 2000–22–04, amendment 39–11950 (65 FR 65257, November 1, 2000), applicable to certain Learjet Model 45 series airplanes, to require repetitive application of grease to the rotating disk assembly of the nose landing gear (NLG) squat switch mechanism. That action was prompted by tests conducted by the manufacturer that indicated a potential unsafe condition exists involving damage or bending of the squat switch assembly of the NLG due to moisture contamination and subsequent formation of ice. The requirements of that AD are intended to prevent bending and damage of the squat switch assembly, which could result in driving the nose wheel to an uncommanded angle against the force of the steering system, and consequently result in the airplane departing the runway at high speeds during landing.

FAA's Determination

In the preamble to AD 2000–22–04, the FAA specified that the actions required by that AD were considered ''interim action,'' and that the manufacturer was developing a modification to positively address the unsafe condition. We indicated that we may consider further rulemaking action once the modification was developed, approved, and available. The manufacturer now has developed such a modification, and we have determined that further rulemaking action is indeed necessary; this proposed AD follows from the determination.

Explanation of Relevant Service Information

Since the issuance of AD 2000–22–04, the FAA has reviewed and approved Bombardier Service Bulletin SB 45–32–8, Revision 2, dated March 14, 2001, including Compliance Response Form. This service bulletin describes procedures for replacement of the camrod in the squat switch assembly of the NLG with a camrod made of stronger material. The replacement constitutes terminating action for the repetitive grease applications required by AD 2000–22–04. This service bulletin also recommends that operators complete the Compliance Response Form. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 2000–22–04 to continue to require repetitive application of grease to the rotating disk assembly of the NLG squat switch mechanism. The proposed AD would require replacement of the camrod in the squat switch assembly of the NLG, and would also reduce the applicability of that AD. The actions would be required to be accomplished in accordance with the service bulletin described previously, except as discussed below.

Difference Between Proposed AD and Service Bulletin

Although the Accomplishment Instructions of Bombardier Service Bulletin SB 45–32–8, Revision 2, dated March 14, 2001, recommend that operators complete the attached Compliance Response Form, this proposed AD would not include such a requirement.

Explanation of Change to Applicability

Operators should note that the applicability of this proposed AD differs from the applicability of AD 2000–22–04. This proposed AD has reduced the applicability to be consistent with the effectivity specified in Bombardier Service Bulletin SB 45–32–8, Revision 2, dated March 14, 2001 (which is referenced as the appropriate source of service information for this proposed AD). Airplanes having serial numbers (S/N) 45–001 through 45–004 inclusive are test airplanes that have either been modified for use as prototypes or destroyed; and airplanes not modified per Bombardier Service Bulletin SB 45–32–3 do not have an NLG squat switch, so they do not have the subject camrod. Therefore, those airplanes are not subject to the unsafe condition addressed in this proposed AD.

Additionally, we have re-identified the airplane model designation as published in the most recent type certificate data sheet for the affected model.

Cost Impact

There are approximately 110 Model 45 airplanes of U.S. registry that would be affected by this proposed AD.

The actions that are currently required by AD 2000–22–04 take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $6,600, or $60 per airplane.

The new actions that are proposed in this AD action would take approximately 3 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $205 per airplane. Based on these figures, the cost impact of the proposed requirements of this AD on U.S. operators is estimated to be $42,350, or $385 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in Ad rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part

39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

2. Section 39.13 is amended by removing amendment 39–11950 (65 FR 65257, November 1, 2000), and by adding a new airworthiness directive (AD), to read as follows:

Learjet: Docket 2002–NM–13–AD. Supersedes AD 2000–22–4, Amendment 39–11950.

Applicability: Model 45 airplanes, certificated in any category; serial numbers (S/N) 45–005 through 45–071 inclusive, that have been modified per Bombardier Service Bulletin 45–32–3; and S/Ns 45–072 through 45–114 inclusive.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent moisture contamination and subsequent formation of ice which could cause bending and damage of the squat switch assembly of the nose landing gear (NLG), driving the nose wheel to an uncommanded angle against the force of the steering system, and consequently resulting in the airplane departing the runway at high speeds during landing, accomplish the following:

Restatement of Requirements of AD 2000–22–04, Amendment 39–11950

Application of Grease

(a) Within 30 days after December 6, 2000 (the effective date of AD 2000–22–04, amendment 39–11950): Apply grease to the rotating disk assembly of the squat switch assembly of the NLG in accordance with Bombardier Service Information Letter SIL 32–016, dated March 30, 2000. Thereafter, repeat this application at intervals not to exceed 30 days until the replacement required by paragraph (b) of this AD is accomplished.

New Requirements of this AD

Terminating Action

(b) Within 300 flight hours or 12 months after the effective date of this AD, whichever occurs first: Replace the camrod of the squat switch assembly of the NLG with a new assembly in accordance with the Accomplishment Instructions of Bombardier Service Bulletin SB 45–32–8, Revision 2, dated March 14, 2001, excluding Compliance Response Form. Accomplishment of the camrod replacement terminates the requirements of this AD.

Alternative Methods of Compliance

(c)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Wichita Aircraft Certification Officer (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

(2) Alternative methods of compliance, approved previously in accordance with AD 2000–22–04, amendment 39–11950, are approved as alternative methods of compliance with this AD.

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

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on May 22, 2003.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13386 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–06–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–11 and –11F Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model MD–11 and –11F airplanes. This proposal would require a one-time inspection of the barrel nut holes of the upper spar caps and skin panel of the horizontal stabilizer for corrosion, and follow-on and corrective actions if necessary. This action is necessary to prevent such corrosion, which could result in structural damage and consequent reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by July 14, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–06–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2002–NM–06–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

FOR FURTHER INFORMATION CONTACT: Ron Atmur, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5224; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light

of the comments received. Submit comments using the following format:

• Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.

• For each issue, state what specific change to the proposed AD is being requested.

• Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2002–NM–06–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–06–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports of water and subsequent corrosion in the barrel nut holes in the area where the outer sections attach to the center section on the left and right sides of the upper horizontal stabilizer on certain MD–11 and –11F airplanes. In one incident, the sealant installed in the barrel nut hole had raised partially out, and severe corrosion was found when the sealant was removed. In two other incidents, removal of the mylar tape and sealant showed that the barrel nut holes were filled with water; investigation revealed that condensation accumulated in the barrel nut holes during flight. Such conditions, if not corrected, could result in structural damage and consequent reduced controllability of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Bulletin MD11–55–023, including Appendix A and Evaluation Form, dated November 28, 2001, which describes procedures for a one-time inspection of the barrel nut holes of the upper spar caps and skin panel of the horizontal stabilizer for corrosion, and follow-on and corrective actions. The follow-on and corrective actions include but are not limited to the following:

• Condition 1—If no corrosion is found, the service bulletin describes procedures to clean, seal, and tape the barrel nut holes per Figure 4 of the service bulletin;

• Condition 2—If corrosion is found that does not exceed the limits specified in Figure 2 of the service bulletin, the service bulletin describes procedures to remove and retain the barrel nuts and bolts, remove the corrosion, and seal and tape the affected barrel nut holes per Figure 2 of the service bulletin; or

• Condition 3—If corrosion is found that does not exceed 0.060 inch on the barrel nut bottom, the service bulletin describes procedures to remove and retain the barrel nuts and bolts, remove the corrosion, fabricate and install bushings, seal and tape the holes, and reinstall the barrel nuts and bolts per Figures 2 of the service bulletin. If corrosion is found in the barrel nut bearing area and/or corrosion exceeds the dimensional limits for each hole, the service bulletin specifies contacting the manufacturer for repair disposition.

The service bulletin also references the procedures in the MD–11 Airplane Maintenance Manual and the Structural Repair Manual for the accomplishment of certain follow-on actions.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously, except that the proposed AD would not require completing the Evaluation Form, and except as discussed below.

Differences Between This Proposed Rule and the Service Information

The service bulletin refers to a ''visual'' inspection. For the purposes of this AD, we have determined that the procedures in the service bulletin constitute a ''detailed inspection.'' Note 2 of this proposed AD defines such an inspection.

Although the service bulletin specifies that the manufacturer may be contacted for disposition of certain repairs, this proposed AD would require such repairs to be accomplished per a method approved by the FAA.

Cost Impact

There are approximately 191 airplanes of the affected design in the worldwide fleet. The FAA estimates that 66 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 6 work hours per airplane to accomplish the proposed inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the inspection proposed by this AD on U.S. operators is estimated to be $23,760, or $360 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation

Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

McDonnell Douglas: Docket 2002–NM–06–AD.

Applicability: Model MD–11 and –11F airplanes, as listed in Boeing Service Bulletin MD11–55–023, dated November 28, 2001, certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent corrosion of the barrel nut holes of the upper spar caps and skin panel of the horizontal stabilizer, which could result in structural damage and consequent reduced controllability of the airplane, accomplish the following:

One-Time Inspection/ Follow-on and Corrective Actions

(a) Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is later: Do a one-time detailed inspection of the barrel nut holes of the upper spar caps and skin panel of the horizontal stabilizer for corrosion, per Boeing Service Bulletin MD11–55–023, including Appendix A, dated November 28, 2001, and excluding Evaluation Form. Before further flight, do the actions required by paragraph (a)(1), (a)(2), (a)(3), or (a)(4) of this AD, as applicable.

Note 2: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

(1) If no corrosion is found: Clean, seal, and tape the barrel nut holes per Figure 4 of the service bulletin.

(2) If corrosion is found that does not exceed the limits specified in Figure 2 of the service bulletin: Remove and retain the barrel nuts and bolts, remove the corrosion of the barrel nut hole, seal and tape the holes per Figure 4 of the service bulletin, and reinstall the barrel nuts and bolts per Figure 2 of the service bulletin.

(3) If corrosion is found that does not exceed 0.060 inch on the barrel nut bottom: Remove and retain the barrel nuts and bolts, remove the corrosion, fabricate and install bushings, seal and tape the holes per Figure 4 of the service bulletin, and reinstall the barrel nuts and bolts per Figure 2 of the service bulletin.

(4) If corrosion is found in the barrel nut bearing area, and/or corrosion exceeds the dimensional limits for each hole specified in Figure 2 of service bulletin: Repair in accordance with a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Special Flight Permit

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on May 22, 2003.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13385 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 75N–183H]

RIN 0910–AA01

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Health-Care Antiseptic Drug Products; Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening until August 27, 2003, the administrative record for the rulemaking for over-the-counter (OTC) topical antimicrobial drug products to accept comments and data concerning OTC health-care antiseptic drug products that have been filed with the Dockets Management Branch, FDA, since the administrative record officially closed. The agency is also providing for the administrative record to remain open until August 27, 2003, to allow for public comment on the comments and data being accepted into the rulemaking. This action is part of FDA's ongoing review of OTC drug products.

DATES: Submit written comments and data or electronic comments by August 27, 2003.

ADDRESSES: Submit written comments and data to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michelle M. Jackson, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has on numerous occasions received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record in a rulemaking proceeding. Under § 330.10(a)(7)(iii) (21 CFR 330.10(a)(7)(iii)), new data and information may be submitted within 12 months after publication of a tentative

final monograph (TFM). Within 60 days after this 12-month period ends, comments on the new data and information may be submitted (see § 330.10(a)(7)(iv)). Under § 330.10(a)(10)(i), the administrative record closes at the end of this 60-day period.

FDA published an amended TFM on OTC topical antimicrobial health-care antiseptic drug products for OTC human use on June 17, 1994 (59 FR 31402). The administrative record for this TFM closed on August 17, 1995. Under § 330.10(a)(7)(v), new data and information submitted after August 17, 1995, prior to the establishment of a final monograph (FM), are considered a petition to amend the monograph and are to be considered only after a FM has been published unless the agency finds that good cause has been shown that warrants earlier consideration. Further, under § 330.10(a)(10)(ii), the agency shall make all decisions and issue all orders under § 330.10 in the FM solely on the basis of the administrative record and shall not consider data or information not included as part of the administrative record.

FDA has received new data and information submitted to the antimicrobial rulemaking after the administrative record closed on August 17, 1995. In some cases, interested persons submitted a petition to reopen the record. In other cases, they submitted new data and information to the Dockets Management Branch as comments on the amended TFM. A number of the petitions and comments submitted to the amended TFM contain new data on proposed nonmonograph (Category II and Category III) ingredients and on the proposed final formulation testing criteria for health-care antiseptic drug products.

Because these data are relevant to the final classification of these ingredients and to the testing criteria to be established in the FM, FDA has determined that good cause exists to consider these new data and information in developing the FM for these products. By this document, FDA announces that it is treating all of these submissions, received after the administrative record closed, as petitions to reopen the administrative record, and is granting the petitions by allowing the new data and information contained therein to be included in the administrative record for the rulemaking for OTC topical antimicrobial health-care antiseptic drug products.

In response to the TFM, the agency received three citizen petitions concerning ingredients that lacked marketing history for the requested use in the United States to be eligible for the OTC drug review (Refs. 1, 2, and 3). The agency has developed a process by which drugs without any marketing experience in the United States could be eligible for consideration in the agency's OTC drug review. This process is described in 21 CFR 330.14. The petitioners were informed to use that process (Refs. 4, 5, and 6). Thus, these citizen petitions are not included as part of the reopening of the administrative record.

II. Reopening of the Administrative Record

Accordingly, the agency is reopening the administrative record for this rulemaking to accept data and information previously submitted to the Dockets Management Branch into the administrative record and to provide interested persons an opportunity to submit comments on these data and information prior to the closing of the record.

The agency is providing a period of 90 days for these comments and new data and information to be submitted. Interested persons have already had an opportunity to submit comments, objections, or requests for an oral hearing on the amended TFM. Therefore, any comments at this time should only address the data and information submitted to the administrative record after August 17, 1995, and should specifically identify the data and information on which the comments are being provided. In addition, only new information related to the submissions being included in the administrative record at this time should be submitted. Any data and information previously submitted to this rulemaking need not be resubmitted. In establishing an FM, the agency will consider only comments, data, and information submitted prior to the closing of the administrative record following this current reopening.

III. Request for Comments

Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) under Docket No. 75N–183H and may be see by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. CP1.
2. Comment No. CP8.
3. Comment No. CP13.
4. Comment No. LET23.
5. Comment No. LET24.
6. Comment No. LET33.

Dated: May 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13317 Filed 5–28–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Chapter I

First Meeting of the Negotiated Rulemaking Committee Established Under the No Child Left Behind Act of 2001

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Announcement of negotiated rulemaking committee meeting.

SUMMARY: The Secretary of the Interior has established a Committee to develop recommendations for proposed rules for Indian education under six sections of The No Child Left Behind Act of 2001. As required by the Federal Advisory Committee Act, we are announcing the date and location of the first meeting of the Negotiated Rulemaking Committee.

DATES: The Committee's first meeting will be held from June 9 to 13, 2003, in Albuquerque, New Mexico.

ADDRESSES: The meeting will be held at the Hyatt Regency Albuquerque, 330 Tijeras Avenue NW., Albuquerque, New Mexico.

FOR FURTHER INFORMATION CONTACT: Barbara James or Shawna Smith, No Child Left Behind Negotiated Rulemaking Project Management Office, PO Box 1430, Albuquerque, NM 87103–1430; telephone (505) 248–7241; fax (505) 248–7242; e-mail *bjames@bia.edu* or *ssmith@bia.edu.* We will post additional information as it becomes available on the Office of Indian Education Programs Web site at *http//www.oiep.bia.edu.*

SUPPLEMENTARY INFORMATION: On May 5, 2003, we published a notice in the **Federal Register** (68 FR 23631)

announcing our intent to form a negotiated rulemaking committee under the No Child Left Behind Act, the Negotiated Rulemaking Act of 1996, and the Federal Advisory Committee Act. The purpose of the Committee is to negotiate and reach consensus on recommendations for proposed rules for Indian education under six sections of The No Child Left Behind Act of 2001. The May 5 notice discussed the issues to be negotiated and the interest group representatives proposed as members of the committee.

The first meeting of the Committee will be held from June 9 to June 13 in Albuquerque, New Mexico. At this meeting, the Committee will address organizational issues such as facilitation, ground rules, schedules, subcommittees, and prioritizing issues. There is no requirement for advance registration for members of the public who wish to attend and observe the meeting. The need to convene the committee as soon as possible in order to meet the schedule for publication of the proposed rule requires that we publish this notice less than 15 days before the meeting date. The agenda for the meeting is as follows:

Agenda for No Child Left Behind Negotiated Rulemaking Committee Meeting

June 9–13, 2003

June 9

Opening—1:30 p.m.
Welcome and Introductions
Background information on Committee tasks
Overview of No Child Left Behind Act provisions for negotiation

June 10

Pre-negotiation workshop—8:30 a.m.
Negotiation of Committee ground rules

June 11

Public comments—8:30 a.m.

Discussion and decision making relating to process

Identification of work groups
Work group meetings

June 12

Public comments—8:30 a.m.
Work group meetings

June 13

Public comments—8:30 a.m.
Selection of Co-Chairs
Work group meetings
Selection of facilitation team
Closing—noon

Dated: May 23, 2003.

Aurene M. Martin,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 03–13485 Filed 5–23–03; 4:20 pm]

BILLING CODE 4310–02–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 70, 72, 75, and 90

RIN 1219–AB14

Verification of Underground Coal Mine Operators' Dust Control Plans and Compliance Sampling for Respirable Dust

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Extension of comment periods.

SUMMARY: We are extending the period for public and post-hearing comment on the proposed rule addressing Verification of Underground Coal Mine Operators' Dust Control Plans and Compliance Sampling for Respirable Dust (Plan Verification), published in the **Federal Register** on March 6, 2003 and on March 17, 2003, respectively.

DATES: We must receive your comments by July 3, 2003.

ADDRESSES: You may use mail, facsimile (fax), or electronic mail to send us your comments. Clearly identify them as comments and send them (1) by mail to MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2313, Arlington, Virginia 22209–3939; (2) by fax to (202) 693–9441; or (3) by electronic mail to: *comments@msha.gov.*

FOR FURTHER INFORMATION CONTACT: Marvin W. Nichols, Jr., Director, Office of Standards, Regulations and Variances, MSHA; phone: (202) 693–9440; facsimile: (202) 693–9441; e-mail: *nichols-marvin@msha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 6, 2003, (68 FR 10784), MSHA published a proposed rule in the **Federal Register** that would require mine operators to verify through sampling the effectiveness of the dust control parameters for each mechanized mining unit (MMU) specified in the approved mine ventilation plan. For samples to be valid, the operator would be required to sample on a production shift during which the amount of material produced by an MMU is at or above the verification production level using only the dust control parameters listed in the ventilation plan.

The use of approved powered, air-purifying respirators (PAPRs) and/or verifiable administrative controls would be allowed as a supplemental means of compliance when MSHA determines that all feasible engineering or environmental controls are being used. The proposed rule would also rescind operator compliance sampling in underground coal mines. The use of a personal, continuous dust monitor (PCDM), once developed and approved, could be used by an operator in conjunction with the dust control parameters specified in the mine ventilation plan. The proposed rule would significantly improve miners' health protection by limiting the exposure of individual miners to respirable coal mine dust.

II. Extension of Comment Periods

The comment periods for the Plan Verification rule were scheduled to close on June 4, 2003 (68 FR 10784, 68 FR 12641). However, in response to requests from the public for additional time to prepare their comments, the comment periods have been extended 30 days until July 3, 2003. All comments must be submitted to MSHA by this date.

Dated: May 9, 2003.

Dave D. Lauriski,

Assistant Secretary of Labor for Mine Safety and Health.

[FR Doc. 03–13528 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

30 CFR Part 72

RIN 1219–AB18

Determination of Concentration of Respirable Coal Mine Dust

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Extension of comment periods.

SUMMARY: We are extending the periods for public and post-hearing comment on the notices reopening the comment period and announcing public hearings on the Determination of Concentration of Respirable Coal Mine Dust (Single Sample), published in the **Federal Register** on March 6, 2003 and on March 17, 2003, respectively.

DATES: We must receive your comments by July 3, 2003.

ADDRESSES: You may use mail, facsimile (fax), or electronic mail to send us your comments. Clearly identify them as comments and send them (1) by mail to MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2313, Arlington, Virginia 22209–3939; (2) by fax to (202) 693–9441; or (3) by electronic mail to: *comments@msha.gov.*

FOR FURTHER INFORMATION CONTACT: Marvin W. Nichols, Jr., Director, Office of Standards, Regulations and Variances, MSHA; phone: (202) 693–9440; facsimile: (202) 693–9441; e-mail: *nichols-marvin@msha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 6, 2003, (68 FR 10940), the Secretaries of Labor and Health and Human Services published a notice, ''Determination of Concentration of Respirable Coal Mine Dust (Single Sample),'' reopening the rulemaking record on a July 7, 2000 joint proposed rule that would determine that the average concentration of respirable dust to which each miner in the active workings of a coal mine is exposed can be accurately measured over a single shift. In that proposed rule the Secretaries proposed to rescind a previous 1972 finding by the Secretary of the Interior and the Secretary of Health, Education and Welfare, on the accuracy of single shift sampling (63 FR 42068).

II. Extension of Comment Periods

The comment periods for the reopening of the Single Sample rule were scheduled to close on June 4, 2003 (68 FR 10940, 68 FR 12641). However, in response to requests from the public for additional time to prepare their comments, the comment periods have been extended 30 days until July 3, 2003. All comments must be submitted to MSHA by this date.

Dated: May 15, 2003.

Elaine L. Chao,

Secretary of Labor.

Dated: May 23, 2003.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

[FR Doc. 03–13441 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–43–P; 4163–70–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

United States Army Restricted Area, New River, Radford Army Ammunitions Plant, Radford, VA

AGENCY: United States Army Corps of Engineers, DoD.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The U. S. Army Corps of Engineers is proposing to establish a restricted area on the New River in the vicinity of the Radford Army Ammunitions Plant, Radford, Virginia. The restricted area will enable the Commanding Officer to enhance security efforts in response to potential terrorist activities. These regulations are necessary to safeguard the facility and are part of a comprehensive plan to protect the public, environment, and economic interests from sabotage and other subversive acts, accidents, or incidents of similar nature.

DATES: Written comments must be submitted on or before June 30, 2003.

ADDRESSES: U.S Army Corps of Engineers, ATTN: CECW–OR, 441 G Street, NW., Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. Frank Torbett, Corps of Engineers Headquarters, Regulatory Branch, Washington, DC at (202) 761–4618, or Mr. Rick Henderson, Corps of Engineers, Norfolk District, Regulatory Branch, at (757) 441–7653.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX, of the Army Appropriations Act of 1919 (40 Stat 892; 33 U.S.C. 3) the Corps proposes to amend the restricted area regulations in 33 CFR part 334 by adding § 334.812 which would establish a restricted area in the New River, at the Radford Army Ammunitions Plant, Radford, Virginia. The public currently has unrestricted access to the facility. The Commanding Officer is seeking authorization from the Corps of Engineers to establish a restricted area in waters of the United States adjacent to the Ammunitions Plant in Radford, Virginia. The District Engineer's preliminary review indicates this request is not contrary to the public interest.

Procedural Requirements

a. *Review under Executive Order 12866.* This proposed rule is issued with respect to a military function of the Defense Department and the provisions of Executive Order 12866 do not apply.

b. *Review under the Regulatory Flexibility Act.* These proposed rules have been reviewed under the Regulatory Flexibility Act (Public Law 96–354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (*i.e.*, small businesses and small Governments). The Corps expects that the economic impact of the establishment of this restricted area would have practically no impact on the public, no anticipated navigational hazard or interference with existing waterway traffic and accordingly, certifies that this proposal if adopted, will have no significant economic impact on small entities.

c. *Review under the National Environmental Policy Act.* An environmental assessment has been prepared for this action. The Norfolk District has concluded, based on the minor nature of the proposed restricted area regulation, that this action, if adopted, will not have a significant impact to the quality of the human environment, and preparation of an environmental impact statement is not required. The environmental assessment may be reviewed at the District office listed at the end of **FOR FURTHER INFORMATION CONTACT,** above.

d. *Unfunded Mandates Act.* This proposed rule does not impose an enforceable duty among the private sector and, therefore, is not a Federal private sector mandate and is not subject to the requirements of Section 202 or 205 of the Unfunded Mandates Act. We have also found under Section 203 of the Act, that small Governments will not be significantly and uniquely affected by this rulemaking.

List of Subjects in 33 CFR Part 334

Danger zones, Marine safety, Navigation (water), Restricted areas, Waterways.

For the reasons set out in the preamble, the Corps proposes to amend 33 CFR part 334, as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

2. Section 334.812 would be added to read as follows:

§ 334. 812 New River, Radford Army Ammunitions Plant, Restricted Area, Virginia.

(a) *The area.* The waters within an area beginning at ordinary high water on the shore at latitude 37°08′59.4″ N, longitude 076°40′15.5″ W; thence along the shoreline to latitude 37°08′58.8″ N, longitude 076°40′06″ W; thence across the river to latitude 37°09′03.1″ N, longitude 076°39′59.4″ W; thence along the shoreline to latitude 37°09′06.9″ N, longitude 076°39′54.1″ W; thence across the river to the point of origin.

(b) *The regulation.* The public shall have unrestricted access and use of the waters adjacent to the Radford Ammunition Plant whenever the facility is in Force Protection Condition Normal Alpha, or Bravo. Whenever the facility is in Force Protection Condition Charlie, all vessels and persons that desire access to the waters of the New River adjacent to the Radford Ammunition plant must agree/submit to an inspection by security personnel to insure they do not pose a threat to the facility. No explosives, explosive devices, chemical or biological agents, handguns, rifles, shotguns, muzzle loaded guns, or other device/devices that would pose a risk to the facility or personnel assigned to the facility will be allowed in the waters designated by this regulation unless written permission is granted by the Commanding Officer, Radford or persons as he/she may delegate this authority to. Once a vessel and/or person has been cleared to enter this restricted area they will be allowed unrestricted use of the waters. Whenever the facility is in Force Protection Delta, the waters, designated in this regulation, will be closed to all traffic and use. The Commanding Officer may authorize exceptions to this regulation as conditions warrant.

(c) *Enforcement.* The regulation in this section, promulgated by the United States Army Corps of Engineers shall be enforced by the Commanding Officer, Radford Ammunitions Plant or persons or agencies as he/she may authorize including any Federal Agency, State, Local or County Law Enforcement agency, or Private Security Firm in the employment of the facility, so long as the entity undertaking to enforce this Restricted Area has the legal authority to do so under the appropriate Federal, State or Local laws.

Dated: April 18, 2003.

Lawrence A. Lang,

Acting Chief, Operations Division, Directorate of Civil Works.

[FR Doc. 03–13451 Filed 5–28–03; 8:45 am]

BILLING CODE 3710–84–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket No. 02–112, CC Docket No. 00–175; FCC 03–111]

Sunset of the BOC Separate Affiliate and Related Requirements and 2000 Biennial Regulatory Review Separate Affiliate Requirements

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this proceeding, the Commission seeks comment on the appropriate classification of Bell Operating Companies' (BOCs) and incumbent independent local exchange carriers' (independent LECs) provision of in-region, interstate and international interexchange telecommunications services. It seeks comment on how changes to the competitive landscape within the interexchange market should affect this classification and on what approach is appropriate for BOCs and independent LECs, if and when these carriers may provide in-region, interexchange services outside of a separate affiliate. The Commission also asks parties to comment on whether there are alternative regulatory approaches, in lieu of dominant carrier regulation, that the Commission could adopt to detect or deter any potential anticompetitive behavior.

DATES: Comments are due June 30, 2003, and Reply Comments are due July 28, 2003.

ADDRESSES: 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Robert Tanner, Attorney-Advisor, and Pamela Megna, Senior Economist, Competition Policy Division, Wireline Competition Bureau, at (202) 418–1580, or via the Internet at *rtanner@fcc.gov* and *pmegna@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Further Notice of Proposed Rulemaking (FNPRM) in WC Docket No. 02–112 and CC Docket No. 00–175, FCC 03–111, adopted May 15, 2003, and released May 19, 2003. The complete text of this FNPRM is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC, 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.* It is also available on the Commission's Web site at *http://www.fcc.gov.*

Synopsis of the Further Notice of Proposed Rulemaking

1. *Background.* In the *Competitive Carrier* proceeding, which included the *Section 272(f)(1) Sunset of the BOC Separate Affiliate and Related Requirements,* Notice of Proposed Rulemaking, WC Docket No. 02–112, (67 FR 42211, June 21, 2002) and the *Section 272(f)(1) Sunset of the BOC Separate Affiliate and Related Requirements,* Memorandum Opinion and Order, WC Docket No. 02–112, (68 FR 6351, February 7, 2003), the Commission established a regulatory framework to distinguish between carriers with market power (*i.e.*, dominant carriers) and those without market power (*i.e.*, non-dominant carriers). Currently, BOCs (with the exception of Verizon in the state of New York where the requirements sunset this past December 23, 2002) are required to provide in-region, interLATA services through a separate section 272 affiliate, and independent LECs are required to provide in-region, interstate services through a separate affiliate. Both types of interexchange affiliates are regulated as non-dominant. Both BOCs and independent LECs are permitted to provide interexchange services out-of-region on an integrated basis and are regulated as non-dominant.

2. The Commission has concluded that the section 272 separate affiliate and related requirements sunset on a state by state basis, and it has allowed the requirements to sunset in New York by operation of law. The Commission has also sought comment in the *2000 Biennial Regulatory Review: Separate Affiliate Requirements of Section 64.1903 of the Commission's Rules* (66 FR 50139, October 2, 2001) proceeding on whether to eliminate the separate affiliate requirements imposed on independent LECs when they provide in-region, domestic interstate or international interexchange services. To the extent that the Commission permits BOCs and independent LECs to provide long distance services on an integrated basis, the FNPRM seeks comment on how these carriers should be classified.

3. *Identification of BOC and Independent LEC In-Region, Interstate and International Interexchange Markets.* The Commission seeks comment on the relevant markets in which BOCs and independent LECs provide these interstate and international interexchange services. The Commission seeks comment on whether the mass market and enterprise markets are the appropriate customer classes for this proceeding. The Commission also asks commenters to consider services provided over traditional wireline local telephone networks as well as comparable services provided over other platforms. This FNPRM seeks comment on the relevant service and geographic markets in which these carriers provide services and the ability of BOCs and independent LECs to exercise market power in any relevant market. The Commission seeks to develop a record on both the retail long distance and upstream access markets.

4. *Market Power Analysis.* The FNPRM recognizes that there have been significant changes in the competitive landscape since the Commission considered whether to categorize the incumbent LECs' long distance affiliates as dominant or non-dominant, including: BOC authority to offer in-region, interLATA services in 41 states (and the District of Columbia); an increase in bundled telecommunications services offerings; an increase in offerings of wide area pricing plans by mobile telephony carriers; and an increase in the provision of Internet-based applications. Accordingly, the Commission seeks comment on how these changes should affect its relevant market and market power analysis.

5. *Appropriate Regulatory Requirements.* The Commission seeks comment on whether there is a continued need for dominant carrier regulation of BOCs' in-region, long distance services after sunset of the section 272 structural and related requirements. In addition, the Commission asks whether it should classify independent LECs as non-dominant or dominant in their provision of in-region, long distance services if it eliminates or modifies the separate affiliate requirements currently imposed on independent LECs. The Commission also seeks comment on alternatives to dominant carrier regulation as a means of addressing any issues that arise when telephone companies provide in-region, long distance services on an integrated basis.

6. The Commission seeks comment on whether the statutory requirements that continue to apply to BOCs under section 272(e) reduce the need for dominant carrier regulation. For instance, the Commission asks parties whether sections 272(e)(1) and (e)(3) provide adequate safeguards to deter anticompetitive behavior and whether the Commission should rely on enforcement activity alone or should adopt additional requirements to implement these provisions.

7. The Commission also asks parties to comment on whether adoption of the measures considered in the Special Access Performance Metrics proceeding would aid enforcement of section 272(e)(1), and thus provide sufficient post-sunset safeguards. In addition, it asks whether similar measures would be appropriate to apply to independent LECs. Finally, the Commission seeks comment on whether additional safeguards are necessary to prevent potential cost misallocation and discrimination.

Initial Regulatory Flexibility Analysis

8. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared the present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this FNPRM. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the Further Notice provided previously. The Commission will send a copy of the FNPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. In addition, the FNPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.

Need for, and Objectives of, the Proposed Rules

9. In this proceeding, the Commission seeks comment on: (1) The appropriate regulatory classification of BOCs for the provision of in-region, interstate and international interexchange services post sunset of the section 272 safeguards; (2) the appropriate regulatory classification of independent LECs for the provision of in-region, interstate and international interexchange services absent the *Fifth Report and Order* requirements; (3) the relevant identification of service markets affecting the provision of in-region, interstate and international interexchange services; and (4) the appropriate regulatory requirements for the provision of in-region, interstate and international interexchange services by BOCs and independent LECs, given current market conditions. The basic elements of the existing dominant carrier regulatory requirements were initially developed some 25 years ago and have focused on constraining the ability of dominant carriers to exercise market power. Application of these requirements to carriers without the ability to leverage market power by restricting output could lead to incongruous results. Thus, the Commission asks interested parties to address whether dominant carrier regulations are well or ill-suited to prevent the risks associated with the BOCs' and independent LECs' provision of in-region, interstate and international interexchange services post section 272 sunset (for the BOCs) and absent the separation safeguards (applicable to independent LECs). The Commission also requests that parties address how it can best balance the goals of deterring BOC and independent LEC anticompetitive and discriminatory behavior and eliminating unnecessary regulation.

Legal Basis

10. The legal basis for any action that may be taken pursuant to the FNPRM is contained in sections 1, 2, 4(i)–4(j), 201, 202, 272 and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i)–4(j), 201, 202, 272 and 303(r).

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

11. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by the proposed rules. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

12. The Commission has included small incumbent LECs in this present RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (*e.g.*, a telephone communications business having 1,500 or fewer employees), and ''is not

dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. It has therefore included small incumbent LECs in this RFA analysis, although the Commission emphasizes that this RFA action has no effect on FCC analyses and determinations in other, non-RFA contexts.

13. *Incumbent Local Exchange Carriers*. Neither the Commission nor the SBA has developed a small business size standard specifically directed toward providers of incumbent local exchange service. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. This provides that such a carrier is small entity if it employs no more than 1,500 employees. Commission data from 2000 indicate that there are 1,329 incumbent local exchange carriers, total, with approximately 1,024 having 1,500 or fewer employees. The small carrier number is an estimate and might include some carriers that are not independently owned and operated; we are therefore unable at this time to estimate with greater precision the number of these carriers that would qualify as small businesses under SBA's size standard. Consequently, the Commission estimates that there are no more than 1,024 ILECS that are small businesses possibly affected by our action.

Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

14. The Commission expects that any proposal we may adopt pursuant to this Further Notice will decrease existing reporting, recordkeeping or other compliance requirements. As noted previously, dominant carriers are currently subject to a broad range of regulatory requirements that are generally intended to protect consumers from unjust and unreasonable rates, terms, and conditions and unreasonable discrimination in the provision of communications services. The Commission's dominant carrier regulation includes rate regulation and tariff filing requirements, and also requires supporting information, which in some cases includes detailed cost data, to be filed by dominant carriers with their tariff filings. Moreover, the Commission has international dominant carrier tariff filing requirements. This FNPRM seeks comment on whether continued dominant carrier regulation is appropriate post sunset of the section 272 separate affiliate requirements on a state-by-state basis, and whether it is necessary to streamline or modify the traditional dominant carrier regulations of BOCs' provision of in-region, interstate and international interexchange services. This FNPRM also seeks comment on whether dominant carrier regulation of independent LECs is necessary should the Commission eliminate the separation requirements currently imposed on such carriers for their provision of in-region, interstate and international interexchange services.

Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

15. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

16. The overall objective of this proceeding is to reduce regulatory burdens on BOCs and independent LECs to the extent consistent with the public interest. The Further Notice seeks specific proposals as to which existing regulations might be removed or streamlined in their application to a BOC's or independent LEC's provision of interstate and international interexchange services absent current safeguards, and asks parties to comment on whether BOCs and independent LECs should be classified as non-dominant in the provision of such services post sunset or, in the case of independent LECs, once separation safeguards are removed. The Further Notice also asks parties to discuss whether, and to what extent, dominant carrier regulation is aptly suited to achieving the Commission's objectives to promote competition and to deter anticompetitive behavior by BOCs and independent LECs. This Further Notice addresses whether there are specific aspects of dominant carrier regulation that continue to be necessary to constrain BOCs and independent LECs from engaging in certain types of anticompetitive behavior, and whether there are specific aspects of the regulations that do not address potential problems that may arise in the interexchange marketplace, absent the separate affiliate requirements. Again, the Commission seeks comment on these matters, especially as they might affect small entities subject to the rules.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

17. None.

Ordering Clauses

18. Pursuant to the authority contained in sections 1, 2, 4(i)–4(j), 201, 202, 272 and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i)–4(j), 201, 202, 272 and 303(r), this FNPRM is adopted.

19. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this FNPRM, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–13231 Filed 5–28–03; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 68, No. 103

Thursday, May 29, 2003

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Board for International Food and Agricultural Development One Hundred and Thirty Eighth Meeting; Notice of Meeting

Pursuant to the Federal Advisory Committee Act, notice is hereby given of the one hundred and thirty-eighth meeting of the Board for International Food and Agricultural Development (BIFAD). The meeting will be held from 8 a.m. to 1 p.m. on June 18, 2003 in the ground floor meeting room of the National Association of State Universities & Land Grant Colleges (NASULGC), at 1307 New York Avenue, NW., Washington, DC.

The BIFAD at this meeting will hear a report and consider recommendations from SPARE (Strategic Partnership for Agricultural Research & Education, a BIFAD committee), following SPARE-led agricultural sub-sector reviews; it will hear a report on USAID-university relationships (a BIFAD-commissioned study); and receive an update on the implementation of the BIFAD Long-Term Training initiative.

The meeting is free and open to the public. Those wishing to attend the meeting or obtain additional information about BIFAD should contact Mr. Lawrence Paulson, the Designated Federal Officer for BIFAD. Write him in care of the U.S. Agency for International Development, Ronald Reagan Building, Office of Agriculture and Food Security, 1300 Pennsylvania Avenue, NW., Room 2.11–073, Washington, DC, 20523–2110 or telephone him at (202) 712–1436 or fax (202) 216–3010.

Lawrence Paulson,

USAID Designated Federal Officer for BIFAD, Office of Agriculture and Food Security, Bureau for Economic Growth, Agriculture & Trade.

[FR Doc. 03–13284 Filed 5–28–03; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: 2001 Panel of the Survey of Income and Program Participation (SIPP), Wave 9 Topical Modules.

Form Number(s): SIPP 21905(L) Director's Letter; SIPP/CAPI Automated Instrument; SIPP 21003 Reminder Card.

Agency Approval Number: 0607–0875.

Type of Request: Revision of a currently approved collection.

Burden: 39,793 hours.

Number of Respondents: 78,750.

Avg Hours Per Response: 30 minutes.

Needs and Uses: The U.S. Census Bureau requests authorization from the Office of Management and Budget (OMB) to conduct the Wave 9 Topical Modules interview for the 2001 Panel of the Survey of Income and Program Participation (SIPP). We also request approval for a few replacement questions in the reinterview instrument. The core SIPP instrument and reinterview instrument were cleared previously. The reinterview instrument will be used for quality control purposes.

The SIPP is designed as a continuing series of national panels of interviewed households that are introduced every few years, with each panel having durations of 3 to 4 years. The 2001 SIPP Panel is scheduled for three years and will include nine waves beginning February 1, 2001.

The survey is molded around a central ''core'' of labor force and income questions that remain fixed throughout the life of a panel. The core is supplemented with questions designed to answer specific needs. These supplemental questions are included with the core and are referred to as ''topical modules.'' The topical modules for the 2001 Panel Wave 9 are Medical Expenses and Utilization of Health Care (Adults and Children), Work Related Expenses and Child Support Paid, and Assets, Liabilities, and Eligibility. Wave 9 interviews will be conducted from October 2003 through January 2004.

Data provided by the SIPP are being used by economic policymakers, the Congress, state and local governments, and Federal agencies that administer social welfare or transfer payment programs, such as the Department of Health and Human Services and the Department of Agriculture. The SIPP represents a source of information for a wide variety of topics and allows information for separate topics to be integrated to form a single and unified database so that the interaction between tax, transfer, and other government and private policies can be examined. Government domestic policy formulators depend heavily upon the SIPP information concerning the distribution of income received directly as money or indirectly as in-kind benefits and the effect of tax and transfer programs on this distribution. They also need improved and expanded data on the income and general economic and financial situation of the U.S. population. The SIPP has provided these kinds of data on a continuing basis since 1983, permitting levels of economic well-being and changes in these levels to be measured over time. Testing of monetary incentives to encourage non-respondents to participate is planned for all waves of the 2001 SIPP Panel.

Affected Public: Individuals or households.

Frequency: Every 4 months.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Section 182.

OMB Desk Officer: Susan Schechter, (202) 395–5103.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Susan Schechter, OMB Desk Officer either by fax (202–395–7245) or email (*susan_schechter@omb.eop.gov*).

Dated: May 22, 2003.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–13368 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Survey of Housing Starts, Sales, and Completions.

Form Number(s): SOC–QI/SF.1, SOC–QI/MF.1.

Agency Approval Number: 0607–0110.

Type of Request: Extension of a currently approved collection.

Burden: 8,725 hours.

Number of Respondents: 24,000.

Avg Hours Per Response: 5 minutes.

Needs and Uses: The U.S. Census Bureau is requesting an extension of the currently approved collection for the Survey of Housing Starts, Sales, and Completions, otherwise known as the Survey of Construction (SOC). The respondents are home builders, real estate agents, rental agents, or new home owners of sampled residential buildings.

The Census Bureau uses the information collected in the SOC to publish estimates of the number of new residential housing units started, under construction, completed, and the number of new houses sold and for sale. Data for two principal economic indicators are produced from the SOC: New Residential Construction (housing starts and housing completions) and New Residential Sales. In addition, a number of other statistical series are produced, including extensive information on the physical characteristics of new residential buildings, and indexes measuring rates of inflation in the price of new buildings.

Government agencies and private companies use statistics from SOC to monitor and evaluate the large and dynamic housing construction industry. For example, the Board of Governors of the Federal Reserve System uses data from this survey to evaluate the effect of interest rates in this interest-rate sensitive area of the economy. The Bureau of Economic Analysis uses the data in developing the Gross Domestic Product (GDP). The private sector uses the information for estimating the demand for building materials and the many products used in new housing and to schedule production, distribution, and sales efforts. The financial community uses the data to estimate the demand for short-term (construction loans) and long-term (mortgages) borrowing.

Affected Public: Business or other for-profit.

Frequency: Monthly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Section 182.

OMB Desk Officer: Susan Schechter, (202) 395–5103.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Susan Schechter, OMB Desk Officer either by fax (202–395–7245) or email (*susan_schechter@omb.eop.gov*).

Dated: May 22, 2003.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–13369 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

[I.D. 052303A]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Southeast Region Dealer and Interview Family of Forms.

Form Number(s): None.

OMB Approval Number: 0648–0013.

Type of Request: Regular submission.

Burden Hours: 397.

Number of Respondents: 85.

Average Hours Per Response: 20 minutes.

Needs and Uses: NOAA proposes to add a reporting requirement to this family for forms. Fishery quotas are established for species in the deep-water and shallow-water management units within the Gulf of Mexico Reef Fish Fishery Management Plan (50 CFR 622.42(a)(ii) and (iii)). Existing methods of monitoring these fishery quotas have proven to be ineffective, and for the past two years landings for the species in these management units have exceeded the quotas. The Southeast Fisheries Science Center intends to use the authority under section 50 CFR 622.5(c)(3)(ii) to require dealers to report purchases (landings) on a monthly basis and every two weeks for the last two months of the season (year).

Affected Public: Business and other for-profit organizations, individuals or households.

Frequency: Monthly, biweekly for last two months of year.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: May 21, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–13422 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

[I.D. 052303B]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the

Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Northwest Region Federal Fisheries Permits.

Form Number(s): None.

OMB Approval Number: 0648–0203.

Type of Request: Regular submission.

Burden Hours: 595.

Number of Respondents: 708.

Average Hours Per Response: 20 minutes for a limited entry permit renewal or transfer; 60 minutes for an experimental fishery permit application; 60 minutes for an experimental fishery permit summary report; 10 minutes for an experimental fishery data report; and 2 minutes for an experimental fishery call-in notification prior to a fishing trip.

Needs and Uses: Two data collections dealing with Federal fishery permits affect participants in the groundfish fishery off Washington, Oregon, and California (WOC). The two data collections involve: (1) Exempted fishing; and (2) limited entry permits for commercial fishermen. Exempted (experimental) fishing permits are issued to applicants for fishing activities that would otherwise be prohibited. The information provided by applications allows NMFS to evaluate the consequences of the exempted fishing activity and weigh the benefits and costs. Permittees are required to file reports on the results of the experiments and in some cases individual vessels are required to provide minimal data reports. There is also a requirement for a call-in notification prior to a fishing trip. This information allows NOAA Fisheries to evaluate techniques used and decide if management regulations should be changed.

A Federal permit is also required to commercially catch groundfish, and permits are endorsed for one or more of three gear types (trawl, longline, and fish pot). Participation in the fishery and access to permits have been limited as a way of controlling the overall fleet harvest capacity. Limited entry permits must be renewed annually and are transferable. Permit owners must fill out renewal forms annually and must fill out transfer forms, as needed.

Affected Public: Business or other for-profit organizations.

Frequency: Annually, on occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: May 21, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–13423 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

[I.D. 052303C]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: American Fisheries Act: Recordkeeping and Reporting Requirements.

Form Number(s): None.

OMB Approval Number: 0648–0401.

Type of Request: Regular submission.

Burden Hours: 1,024.

Number of Respondents: 26.

Average Hours Per Response: 20 hours for a cooperative preliminary report; 8 hours for a cooperative final report; 30 minutes for a non-member vessel contract fishing application; 35 minutes for a shoreside processor electronic logbook (SPELR); 5 minutes for a cooperative pollock catch report; and 5 minutes for a designation of agent for service of process.

Needs and Uses: On October 21, 1998, the President signed into law the American Fisheries Act (AFA), which imposed major structural changes on the Bering Sea and Aleutian Islands Management Area (BSAI) pollock fishery. The purpose of the AFA was to tighten U.S. ownership standards that had been exploited under the Antireflagging Act, and to provide the BSAI pollock fleet with the opportunity to conduct their fishery in a more rational manner while protecting non-AFA participants in the other fisheries. The AFA also affected the management of other groundfish, crab, and scallop fisheries off Alaska. Much of the monitoring and enforcement burden is placed on participating AFA cooperatives and their members, which allows NOAA to manage the pollock fishery more precisely. Monitoring their own catch, vessels are able to individually (and in aggregate) come very close to harvesting exactly the amount of pollock they were allocated.

Affected Public: Business or other for-profit organizations.

Frequency: On occasion, annually, recordkeeping.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395-3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482-0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: May 21, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–13424 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

[I.D. 052303D]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Gulf of Mexico Red Snapper Individual Fishing Quota Referendum Data Collection.

Form Number(s): None.

OMB Approval Number: None.

Type of Request: Regular submission.

Burden Hours: 102.

Number of Respondents: 200.

Average Hours Per Response: 10 minutes for an initial referendum response; 20 minutes for a subsequent referendum response; and 10 minutes

for information regarding vessel captains.

Needs and Uses: NOAA National Marine Fisheries Service (NMFS) needs this data collection to properly implement the referendum procedures specified in the Magnuson-Stevens Fishery Conservation and Management Act (Act). The Act provides that on or after October 1, 2000, the Gulf of Mexico Fishery Management Council may prepare and submit a fishery management plan, plan amendment, or regulation for the Gulf of Mexico commercial red snapper fishery that creates an individual fishing quota (IFQ) program or that authorizes the consolidation of licenses, permits, or endorsements that result in different trip limits for vessels in the same class. These actions can only take place if the preparation of such plan, amendment, or regulation is approved in a referendum, and only if the submission to the Secretary of such plan, amendment, or regulation is approved in a subsequent referendum. NMFS also needs to gather data about vessel captains, who are eligible to participate in the referenda, from permit holders with red snapper endorsements.

Affected Public: Business or other for-profit organizations, individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: May 21, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–13425 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–557–812, A–570–884]

Notice of Initiation of Antidumping Duty Investigations: Certain Color Television Receivers From Malaysia and the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Initiation of antidumping duty investigations.

EFFECTIVE DATE: May 29, 2003.

FOR FURTHER INFORMATION CONTACT: Irina Itkin at (202) 482–0656, or Michael Strollo at (202) 482–0629, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Initiation of Investigations

The Petitions

On May 2, 2003, the Department of Commerce (''the Department'') received petitions filed in proper form by Five Rivers Electronic Innovations, LLC (''Five Rivers''), the International Brotherhood of Electrical Workers (''IBEW''), and the Industrial Division of the Communications Workers of America (''IUE-CWA'') (collectively ''the petitioners'').

In accordance with section 732(b)(1) of the Tariff Act of 1930 (''the Act''), the petitioners allege that imports of color television receivers (''CTVs'') from Malaysia and the People's Republic of China (''the PRC''), are, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that imports from Malaysia and the PRC, are materially injuring, or are threatening to materially injure, an industry in the United States.

The Department finds that the petitioners filed these petitions on behalf of the domestic industry because they are interested parties as defined in sections 771(9)(C) and 771(9)(D) of the Act and they have demonstrated sufficient industry support with respect to each of the antidumping investigations that they are requesting the Department to initiate. *See infra,* ''Determination of Industry Support for the Petitions.''

Scope of Investigations

For purposes of these investigations, the term ''certain color television receivers'' includes complete and incomplete direct-view or projection-type cathode-ray tube color television receivers, with a video display diagonal exceeding 52 centimeters, whether or not combined with video recording or reproducing apparatus, which are capable of receiving a broadcast television signal and producing a video image. Specifically excluded from these investigations are computer monitors or other video display devices that are not capable of receiving a broadcast television signal.

The color television receivers subject to these investigations are currently classifiable under subheadings 8528.12.2800, 8528.12.3250, 8528.12.3290, 8528.12.4000, 8528.12.5600, 8528.12.3600, 8528.12.4400, 8528.12.4800, and 8528.12.5200 of the *Harmonized Tariff Schedule of the United States* (''HTSUS''). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the merchandise under investigation is dispositive.

As discussed in the preamble to the Department's regulations *(Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997)), we are setting aside a period for parties to raise issues regarding product coverage. The Department encourages all parties to submit such comments within 20 calendar days of publication of this notice. Comments should be addressed to Import Administration's Central Records Unit, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and consult with parties prior to the issuance of the preliminary determinations.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that the Department's industry support determination, which is to be made before the initiation of the investigation, be based on whether a minimum percentage of the relevant industry supports the petition. A petition meets this requirement if the domestic producers or workers who support the petition account for: (1) At least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the

petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A), or (ii) determine industry support using a statistically valid sampling method.

Section 771(4)(A) of the Act defines the ''industry'' as the producers of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (''ITC''), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to the law.[1]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation,'' *i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition.

In their initial petitions and subsequent submissions, the petitioners state that they comprise well over 50 percent of U.S. CTV production. The petitions identify three additional U.S. companies engaged in the production of CTVs, none of which have taken a position on (either for or against) the petitions. Through data provided by the petitioners and our own independent research, we have determined that the CTV production of these three companies is not high enough to place the petitioners' industry support in jeopardy. Based on all available information, we agree that the petitioners comprise over 50 percent of all domestic CTV production.

Our review of the data provided in the petition and other information readily available to the Department indicates that the petitioners have established industry support representing over 50 percent of total production of the domestic like product, requiring no further action by the Department pursuant to section 732(c)(4)(D) of the Act. In addition, the Department received no opposition to the petitions from domestic producers of the like product. Therefore, the domestic producers or workers who support the petitions account for at least 25 percent of the total production of the domestic like product, and the requirements of section 732(c)(4)(A)(i) of the Act are met. Furthermore, the domestic producers or workers who support the petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for or opposition to the petitions. Thus, the requirements of section 732(c)(4)(A)(ii) of the Act also are met. Accordingly, the Department determines that the petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

With regard to the definition of domestic like product, the petitioner does not offer a definition of domestic like product distinct from the scope of the investigations. On May 19, 2003, Funai Electric Malaysia Sdn., Bhd., and Funai Corporation, Inc., a Malaysian producer of the subject merchandise and importer/reseller, respectively (collectively known as ''Funai''), challenged industry support for the petitions, in accordance with section 732(c)(4)(E) of the Act. In addition, on May 20, 2003, Sichuan Changhong Electric Co., Ltd. also challenged industry support for the petitions. On May 21, 2003, the petitioners filed their reply to both of these challenges.

Based on our analysis of the information presented by the petitioners, we have determined that there is a single domestic like product, CTVs, which is defined in the ''Scope of Investigations'' section above, and we have analyzed industry support in terms of this domestic like product. For more information on our analysis and the data upon which we relied, *see* Import Administration Antidumping Investigation Initiation Checklist (''Initiation Checklist''), Industry Support section and Appendix 1, dated May 22, 2003, on file in the Central Records Unit of the main Department of Commerce building.

Export Price and Normal Value

The following are descriptions of the allegations of sales at less than fair value upon which the Department based its decision to initiate these investigations. The sources of data for the deductions and adjustments relating to U.S. and foreign market prices, constructed value (''CV''), and factors of production are discussed in greater detail in the Initiation Checklist. Should the need arise to use any of this information as facts available under section 776 of the Act in our preliminary or final determinations, we may re-examine the information and revise the margin calculations, if appropriate.

Regarding an investigation involving a non-market economy (''NME'') country, the Department presumes, based on the extent of central government control in an NME, that a single dumping margin, should there be one, is appropriate for all NME exporters in the given country. In the course of these investigations, all parties will have the opportunity to provide relevant information related to the issues of a country's NME status and the granting of separate rates to individual exporters. *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585, 22586–87 (May 2, 1994).

Malaysia

Export Price

The anticipated POI for Malaysia is April 1, 2002, through March 31, 2003.

The petitioners based export price (''EP'') on a U.S. port price quote within the period of investigation (''POI'') for the direct sale of 27-inch CTVs produced in Malaysia by Funai to an unaffiliated customer in the United States. The petitioners calculated a net U.S. price by deducting foreign inland freight. *See* the Initiation Checklist.

Because the petitioners provided price quotes for actual products and we determine that these price quotes are sufficient for initiation purposes, we did not use the average unit values calculated from U.S. import statistics that the petitioners provided because they are based on a broad basket HTSUS category. To the extent necessary, we will consider the appropriateness of the petitioners' alternative methodology during the course of this proceeding.

[1] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (Ct. Int'l Trade 2001), *citing Algoma Steel Corp. Ltd.* v. *United States,* 688 F. Supp. 639, 642–44 (Ct. Int'l Trade 1988) (''the ITC does not look behind ITA's determination, but accepts ITA's determination as to which merchandise is in the class of merchandise sold at LTFV'').

For our complete analysis of EP, see the Initiation Checklist

Normal Value

The petitioners based normal value (''NV'') on third-country price quotes and offers for sale by Funai because they were unable to obtain price information for any Malaysian producer in the home market. During the course of our initiation, we obtained information which indicated that there is no viable home market for CTVs in Malaysia because all Malaysian-produced CTVs are exported. *See* the May 16, 2003, memorandum to the File from Irina Itkin, Elizabeth Eastwood, and Jim Nunno entitled ''Telephone Conversation with Foreign Market Researcher.'' The petitioners focused on Funai when seeking a price quote for NV because this company is the largest CTV producer in Malaysia and a price quote from this company forms the basis for U.S. price.

In selecting the third-country market, the petitioners chose Japan because it is the largest third-country market for CTVs produced by Funai. Moreover, the product subject to the Japan price quote is comparable to the product exported to the United States which served as the basis for EP. After examining this evidence, we found the petitioners' selection of Japan as the comparison market to be reasonable.

The petitioners made adjustments for consumption tax, movement expenses, and third-country and U.S. credit expenses. The petitioners based the amounts for third country and U.S. interest rates on lending rates contained in *International Financial Statistics* published by the International Monetary Fund. The petitioners converted NV into U.S. dollars using the annual average 2002 yen/U.S. dollar exchange rate calculated based on the exchange rates posted on the Department's Web site. We revised the petitioners' calculation of NV to correct an error in the consumption tax and the calculation of the average exchange rate. *See* the Initiation Checklist.

Pursuant to section 773(b) of the Act, the petitioners provided information demonstrating reasonable grounds to believe or suspect that sales by Malaysian producers in the relevant foreign market were made at prices below the cost of production (''COP'') and, accordingly, requested that the Department conduct a country-wide sales-below-COP investigation in connection with this investigation. The Statement of Administrative Action (''SAA''), submitted to the Congress in connection with the interpretation and application of the URAA, states that an allegation of sales below COP need not be specific to individual exporters or producers. SAA, H.R. Doc. No. 103–316 at 833 (1994). The SAA, at 833, states that ''Commerce will consider allegations of below-cost sales in the aggregate for a foreign country, just as Commerce currently considers allegations of sales at less than fair value on a country-wide basis for purposes of initiating an antidumping investigation.''

Further, the SAA provides that section 773(b)(2)(A) of the Act retains the requirement that the Department have ''reasonable grounds to believe or suspect'' that below-cost sales have occurred before initiating such an investigation. Reasonable grounds exist when an interested party provides specific factual information on costs and prices, observed or constructed, indicating that sales in the foreign market in question are at below-cost prices. *Id.*

Pursuant to section 773(b)(3) of the Act, COP consists of the cost of manufacturing (''COM''); selling, general, and administrative expenses (''SG&A''); financial expenses; and packing expenses. The petitioners stated that they were unable to obtain information concerning Funai's actual CTV COP data. Therefore, the petitioners calculated COM based on the costs incurred by an Indian producer of CTVs with a production process similar to Funai's, adjusted for known differences between costs incurred to produce CTVs in India and Malaysia. To calculate SG&A and financial expenses, the petitioners relied upon amounts reported in the 2002 consolidated financial statements of Funai. The petitioners based packing costs on the Indian producer's experience.

Based on a comparison of the Japanese market prices for CTVs to the COP calculated in the petition, we find reasonable grounds to believe or suspect that sales of the foreign like product were made at prices below COP within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating a country-wide cost investigation relating to third-country sales to Japan. We note, however, that if we determine that the home market (*i.e.*, Malaysia) is viable, our initiation of a country-wide cost investigation with respect to sales to Japan will be rendered moot.

Pursuant to sections 773(a)(4), 773(b) and 773(e) of the Act, the petitioners also based NV for sales in the United States on CV. The petitioners calculated CV using the same COM, SG&A, and financial expense figures used to compute the Japanese third-country market costs. Consistent with 773(e)(2) of the Act, the petitioners included in CV an amount for profit. For profit, the petitioners relied upon amounts reported in Funai's 2002 consolidated financial statements. The petitioners adjusted CV to make a circumstance-of-sale adjustment for credit expenses, in accordance with the Department's statutory EP calculation methodology. We revised the petitioners' calculation of CV to correct an error in the average exchange rate, as noted above. For our complete analysis of NV, see the Initiation Checklist.

The estimated dumping margin in the petition for Malaysia based on a comparison between EP and the third-country price is 30.89 percent. Our recalculation, as described above, resulted in a margin of 30.88 percent. The estimated price-to-CV margin in the petition is 47.76 percent. The adjusted price-to-CV comparison resulted in an estimated dumping margin of 47.02 percent.

The PRC

Export Price

The anticipated POI for the PRC is October 1, 2002, through March 31, 2003.

The petitioners based EP on price quotes within the POI for the sale of 27-inch curved and flat-screen CTVs produced in the PRC to an unaffiliated customer in the United States. The petitioners calculated net U.S. prices by deducting foreign brokerage and handling expenses, international freight expenses, U.S. customs duties, and U.S. inland freight expenses.

Because the petitioners provided price quotes for actual products and we determine that these price quotes are sufficient for initiation purposes, we did not use the average unit values calculated from U.S. import statistics that the petitioners provided as a second basis to estimate dumping margins. To the extent necessary, we will consider the appropriateness of the petitioners' alternative methodology during the course of this proceeding. For our complete analysis of EP, *see* the Initiation Checklist.

Normal Value

The petitioners allege that the PRC is an NME country, and that in all previous investigations the Department has determined that the PRC is an NME. *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Saccharin from the People's Republic of China,* 68 FR 27530 (May 20, 2003). In accordance with section 771(18)(C) of the Act, any determination that a foreign

country has at one time been considered an NME shall remain in effect until revoked. Therefore, the PRC will continue to be treated as an NME unless and until its NME status is revoked. Pursuant to section 771(18)(C)(i) of the Act, because the PRC's status as an NME remains in effect, the petitioners determined the dumping margin using an NME analysis.

The petitioners assert that India is the most appropriate surrogate country for the PRC, claiming that India is: (1) A market economy; (2) a significant producer of comparable merchandise; and (3) at a level of economic development comparable to that of the PRC in terms of per-capita gross national income. Based on the information provided by the petitioners, we believe that the petitioners' use of India as a surrogate country is appropriate for purposes of initiation of this investigation.

The petitioners valued the factors of production using the quantities of inputs reported by an Indian CTV producer, because public information about PRC factor quantities for production of 27-inch curved-screen and 27-inch flat-screen CTVs was not reasonably available. The factors of production and usage amounts were derived from the actual production records of the Indian surrogate generated for both 27-inch curved-screen and 27-inch flat-screen CTVs during the period October 2002 through March 2003.

Values for color picture tubes, chassis, cabinets, remote controls with tuners, assorted components, and packing materials were based on the actual costs incurred by the Indian CTV manufacturer relied upon for the usage amounts discussed above. Labor was valued using the Department's regression-based wage rate for the PRC, in accordance with 19 CFR 351.408(c)(3). Electricity was valued based upon the 2001–2002 annual report of BPL Display Devices, Ltd., a publicly traded Indian color picture tube producer. All surrogate values that fell outside the anticipated period of investigation, which in the PRC case is October 1, 2002, through March 31, 2003, were adjusted for inflation.

The petitioners based their calculations of factory overhead, SG&A expenses, and profit on the average of the rates reported in the 2001–2002 annual reports of BPL Ltd. (''BPL'') and Onida Saka (''Onida''), Indian producers of CTVs, and the 2000–2001 annual report of Videocon International, Ltd. (''Videocon''), a third Indian producer of CTVs. As the annual report of Videocon was less contemporaneous with the POI than those of BPL and Onida, we revised the calculation of factory overhead, SG&A expenses, and profit to exclude Videocon's data.

Based on the information provided by the petitioners, we believe that the surrogate values represent information reasonably available to the petitioners and are acceptable for purposes of initiation of this investigation. For our complete analysis of NV, *see* the Initiation Checklist.

The estimated dumping margins in the petition for the PRC based on a comparison of EP to NV are as follows: for 27-inch curved screen CTVs, 50.94 percent; and for 27-inch flat screen CTVs, 80.16 percent. However, based upon comparisons of EP to the adjusted NV, the revised estimated dumping margins are as follows: for 27-inch curved screen CTVs, 49.50 percent; and for 27-inch flat screen CTVs, 78.45 percent.

Fair Value Comparisons

Based on the data provided by the petitioners, there is reason to believe that imports of CTVs from Malaysia and the PRC are being, or are likely to be, sold at less than fair value.

Allegations and Evidence of Material Injury and Causation

With regard to both Malaysia and the PRC, the petitioners allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the individual and cumulated imports of the subject merchandise sold at less than NV.

The petitioners contend that the industry's injured condition is evident in the declining trends in net operating profits, net sales volumes, profit-to-sales ratios, production employment, and capacity utilization. The allegations of injury and causation are supported by relevant evidence including U.S. Bureau of Customs and Border Protection import data, lost sales, and pricing information. We have assessed the allegations and supporting evidence regarding material injury and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation. *See* the Initiation Checklist.

Initiation of Antidumping Investigations

Based upon our examination of the petitions on CTVs, we have found that they meet the requirements of section 732 of the Act. Therefore, we are initiating antidumping duty investigations to determine whether imports of CTVs from Malaysia and the PRC are being, or are likely to be, sold in the United States at less than fair value. Unless this deadline is extended pursuant to section 733(b)(1)(A) of the Act, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act, a copy of the public version of each petition has been provided to the representatives of the governments of Malaysia and the PRC. We will attempt to provide a copy of the public version of each petition to each exporter named in the petitions, as provided for under 19 CFR 351.203(c)(2).

ITC Notification

We have notified the ITC of our initiations as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine no later than June 16, 2003, whether there is a reasonable indication that imports of CTV's from Malaysia and the PRC are causing material injury, or threatening to cause material injury, to a U.S. industry. A negative ITC determination for either country will result in the investigation being terminated with respect to that country; otherwise, these investigations will proceed according to statutory and regulatory time limits.

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: May 22, 2003.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 03–13453 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 012303A]

Small Takes of Marine Mammals Incidental to Specified Activities; Port of Miami Construction Project (Phase II)

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

ACTION: Notice of issuance of an incidental harassment authorization.

SUMMARY: In accordance with provisions of the Marine Mammal Protection Act (MMPA), notification is hereby given that an Incidental Harassment Authorization (IHA) has been issued to the U.S. Army Corps of Engineers-Jacksonville District (Corps) to take small numbers of bottlenose dolphins (*Tursiops truncatus*), by harassment, incidental to deepening the Dodge-Lummus Island Turning Basin in Miami, FL (Turning Basin).

DATES: This authorization is effective from May 22, 2003, through May 22, 2004.

ADDRESSES: A copy of the application may be obtained by writing to Kimberly Skrupky, Office of Protected Species, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, Md 20910, or by telephoning the contact listed here.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Hollingshead, NMFS, (301) 713–2322, ext 128.

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 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.

NMFS has found that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses and that the permissible methods of taking and requirements pertaining to the 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.

Subsection 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. 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''].

Subsection 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 small numbers of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

On June 24, 2002, NMFS received a request from the Corps for an IHA to take bottlenose dolphins, by harassment, incidental to deepening the Turning Basin in the Port of Miami, south of Dodge-Lummus Island. The Corps has formulated equations for confined charges, based on the Navy Diver Formula, to determine zone radii for three zones:

Caution Zone Radius = 260(lbs explosives/delay)⅓

Safety Zone Radius = 520 (lbs explosives/delay)⅓

Watch Zone Radius = 3(260(lbs explosives)1/3)

The Caution Zone is the radius from an open-water blast where mortality will not occur. Detonation will not occur if a marine mammal is known to be within this area. The Safety Zone is the radius from an open-water blast where injury will not occur. The Watch Zone is three times the Caution Zone where observers will conduct a watch before and after the detonation.

A notice of receipt of the application and proposed authorization was published on February 6, 2003 (68 FR 6116). That notice described the activity and anticipated effects on marine mammals. NMFS received one comment letter from the Marine Mammal Commission (Commission) on the application and proposed authorization.

Comment 1: The Commission agrees that, unless animals are close to the source or exposure is frequent, the actions are negligible. They note, however, that it would be useful if NMFS or the applicant conducted pre- and post- blast surveys, and monitored and mapped the distribution of high-intensity sound resulting from the shallow-water blasts.

Response: NMFS recognizes that while acoustic measurements would be helpful, they too expensive relative to this single blasting project. Surveys will be conducted both prior to and post-blasting. A marine mammal watch will be conducted by no less than 2 qualified observers from a small watercraft at for at least 30 minutes before and after the time of each detonation, in the watch zone calculated for an open water blast.

Comment 2: Survey data may be available concerning the numbers of dolphins and other marine mammals in, and their use of, the Dodge-Lummus Island Turning Basin area. If so, they should be provided to NMFS. If not, NMFS may want to require that the applicant conduct such surveys prior to initiating the proposed activities.

Response: The Corps provided information regarding a survey conducted by the NMFS, Southeast Fisheries Science Center, Miami Laboratory. NMFS has been conducting a photo-identification survey of the dolphins in Biscayne Bay since 1990. The study area encompasses an area of approximately 200 mi2. This study area ranged from Haulover Inlet south to the Card Sound Bridge behind Key Largo. The study has identified 159 individual animals residing in Biscayne Bay, 146 of which have been resighted on at least one additional time. Many of these animals have been sighted within or transiting through the Port of Miami. Population studies conducted by the Southeast Fisheries Science Center have found that the size of the subpopulation of bottlenose dolphins in Biscayne averages between 78 and 92 individuals (Joe Contillo, pers. com. May 5, 2003).

Comment 3: NMFS should advise the Corps that manatees have been observed in this area. If there is the potential that manatees will also be taken incidental to the proposed activities, authorization for such taking would be needed from the U.S. Fish and Wildlife Service.

Response: The Corps completed consultation with the USFWS for this project on June 19, 2002. The USFWS concurred with the Corps that activities associated with the Corps' dredging project in the D-L-I Turning Basin were not likely to adversely affect listed species.

Comment 4: An across-the-board definition of temporary threshold shift (TTS) as constituting no more than Level B harassment inappropriately dismisses possible injury and biologically significant behavioral effects (e.g., an increased risk of natural predation or ship strikes) that can result from repeated TTS harassment and from the cumulative effects of long-term exposure. The Commission therefore reiterated it recommendation that TTS be considered as having the potential to injure marine mammals (i.e., Level A harassment).

Response: NMFS has addressed the concern of the definition of TTS in previous small take authorizations (66 FR 22450, May 4, 2001; 67 FR 46712, July 16, 2002). These authorizations state that the best scientific information available supports NMFS' determination that TTS results in Level B harassment, rather than Level A harassment. Because TTS is unlikely to occur in bottlenose dolphins from this project (due to mitigation and monitoring discussed in this document), additional discussion is not warranted at this time.

Mitigation and Monitoring

NMFS is requiring the Corps to implement mitigation measures and a monitoring program that will establish caution-zone radii to ensure that bottlenose dolphins will not be injured during blasting and that impacts will be at the lowest level practicable. Mitigation measures include: (1) confining the explosives in a hole with drill patterns restricted to a minimum of 8 ft (2.44 m) separation from any other loaded hole; (2) restricting the hours of detonation from 2 hours after sunrise to 1 hr before sunset to ensure adequate observation of marine mammals and sea turtles in the safety zone; (3) staggering the detonation for each explosive hole in order to spread the explosive's total overpressure over time, which in turn will reduce the caution zone radius; (4) capping the hole containing explosives with rock in order to reduce the outward potential of the blast, thereby reducing the chance of injuring a dolphin or sea turtle; (5) matching, to the extent possible, the energy needed in the ''work effort'' of the borehole to the rock mass to minimize excess energy vented into the water column; and (6) conducting a marine mammal/sea turtle watch with no less than two qualified observers from a small water craft and/or an elevated platform on the explosives barge, for at least 30 minutes before and for 30 minutes after each detonation to ensure that there are no dolphins or sea turtles in the area at the time of detonation. The observer monitoring program will take place in the watch zone. Any marine mammal in the caution zone or the watch zone will not be forced to move out of those zones by human intervention. Detonation shall not occur until the animal moves out of the caution zone on its own volition.

In the unlikely event a marine mammal or marine turtle is injured or killed during blasting, the Contractor shall notify the Corps and the NMFS Regional Office within 48 hours. In addition, the Contractor will also notify the Florida Marine Patrol and the USFWS in Vero Beach.

Reporting

The Corps anticipates completing the proposed activities within 24 months of the start date. Therefore, NMFS is issuing a 1–year IHA with the possibility for renewal upon application from the Corps. NMFS requires the Corps to submit a report of activities 120 days before the expiration of the proposed IHA if the Corps plans to request a renewal of its IHA, or 120 days after the expiration of the IHA if a renewal is not being requested.

Endangered Species Act

Under section 7 of the ESA, the Corps completed consultation with NMFS on September 23, 2002, and with the USFWS on June 19, 2002, for this project. Both agencies found that activities associated with the Corps' dredging project in the Dodge-Lummus Island Turning Basin were not likely to adversely affect listed species.

National Environmental Policy Act

In accordance with section 6.01 of the National Oceanic and Atmospheric Administration (NOAA) Administrative Order 216–6 (Environmental Review Procedures for Implementing the National Environmental Policy Act, May 20, 1999), NMFS has analyzed both the context and intensity of this action and determined, based on the Corps' 1989 Environmental Impact Statement and Feasibility Report for the Navigation Study for the Miami Harbor Channel and the contents, results, and analyses of the Corps' blasting project, that this IHA will not individually or cumulatively result in a significant impact on the quality of the human environment as defined in 40 CFR 1508.27. Accordingly, this action qualifies for a categorical exemption and is exempted from further environmental review under NOAA Administrative Order 216–6.

Conclusions

NMFS determined that the short-term impact as described in the proposed authorization (68 FR 6116, February 6, 2003), should result, at worst, in the temporary modification in behavior by bottlenose dolphins. Although behavioral modifications, including temporarily vacating the area, may be made by this species to avoid the resultant visual and acoustic disturbance from dredging and detonations, this action is expected to have a negligible impact on the affected species or stocks. In addition, no take by injury and/or death is anticipated, and harassment takes will be at the lowest level practicable due to incorporation of the mitigation measures mentioned previously in this document.

Authorization

NMFS has issued an IHA to the Corps for the potential harassment of small numbers of bottlenose dolphins incidental to deepening the Turning Basin in Miami, FL, provided the previously described mitigation, monitoring, and reporting requirements are met. NMFS has determined that the activity would result in the Level B harassment of only small numbers of bottlenose dolphins and will have no more than a negligible impact on this marine mammal stock.

Dated: May 22, 2003.

Donna Wieting,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 03–13426 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Practitioner Records Maintenance, Disclosure, and Discipline Before the Patent and Trademark Office (Formerly Practitioner Records Maintenance and Disclosure Before the Patent and Trademark Office)

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), 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 the revision of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before July 28, 2003.

ADDRESSES: Direct all written comments to Susan K. Brown, Records Officer, Office of Data Architecture and Services, Data Administration Division, U.S. Patent and Trademark Office, Suite 310, 2231 Crystal Drive, Arlington, VA 22202, by telephone at (703) 308–7400; by e-mail at *susan.brown@uspto.gov*; or by facsimile at (703) 308–7407.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the attention of Nora Cordova, Mail Stop OED, Director of the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313–1450; by

telephone at (703) 306–4097; or by electronic mail at *nora.cordova@uspto.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Director of the United States Patent and Trademark Office (USPTO), under the direction of the Department of Commerce, has the authority to establish regulations for the conduct of proceedings before the agency and to prescribe regulations governing the conduct and discipline of agents, attorneys, or other persons representing applicants and other parties before the USPTO (35 U.S.C. 2, 32 and 33). The USPTO Code of Professional Responsibility (37 CFR 10.20 to 10.112) describes how attorneys or practitioners should conduct themselves professionally and outlines their responsibilities for record keeping and reporting violations or complaints of misconduct to the USPTO, while the Investigations and Disciplinary Proceedings rules (37 CFR 10.130 to 10.170) outline how the USPTO can discipline attorneys and practitioners.

The USPTO Code of Professional Responsibility requires that an attorney or agent maintain complete records of all funds, securities, and other properties of clients coming into his or her possession, and to render appropriate accounts to the client regarding the funds, securities, and other properties. These record keeping requirements are necessary to maintain the integrity of client property. Similar record keeping is required by each State Bar of its attorneys.

The Code also requires that an attorney or agent will report knowledge of certain violations of the Code to the USPTO. This collection requirement is necessary to investigate and possibly prosecute violations of the USPTO Code. If the complaint is found to have merit, the USPTO will provide the practitioner with the opportunity to respond to the complaint. The practitioner can request one 30-day extension of time to respond to the complaint. The USPTO also provides practitioners with the opportunity to respond to settlement offers. The Director may, after notice and opportunity for a hearing, suspend, exclude, or disqualify any practitioner from further practice before the USPTO based on noncompliance with the regulations established under the United States Code.

The information collected (reports of alleged violations of the USPTO Code of Professional Responsibility) is used by the Director of Enrollment and Discipline (OED) to conduct investigations and prosecute violations as appropriate. If this information is not collected, the Director of OED would have no knowledge of alleged violations and would be unable to enforce this provision of the USPTO Code.

The USPTO plans to publish a notice of proposed rulemaking, ''Changes to Representation of Others Before the United States Patent and Trademark Office'' in the **Federal Register**. This proposed rulemaking expands existing record keeping requirements. Under this proposed rulemaking, practitioners must keep copies or recordings of advertisements or communications disseminated in print or electronic media for two years after the last use of the advertisement, along with a record of when and where the advertisement was used. Additionally, practitioners who have been excluded or suspended from practice before the USPTO must keep and maintain records of their steps to comply with the suspension or exclusion order. These records serve as the practitioner's proof of compliance with the order.

Existing information requirements overlooked in previous submissions are being added to this collection for the first time. The USPTO has reviewed these requirements and determined that they should be submitted to OMB for review. Therefore, the Responses to Requests/Requirements for Information, Requests for Extensions of Time to Respond, Responses to Settlement Offers, and Responses to Show Cause are being incorporated into this collection.

II. Method of Collection

By mail, facsimile, or hand delivery to the USPTO when an individual is required to participate in the information collection.

III. Data

OMB Number: 0651–0017.

Form Number(s): There are no forms associated with this collection.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions, the Federal Government, and State, Local, or Tribal Government.

Estimated Number of Respondents: 582 responses per year.

Estimated Time Per Response: The USPTO estimates that practitioners spend 26 hours per year keeping and maintaining records concerning their client's cases. The USPTO estimates that practitioners seeking reinstatement to practice before the agency will spend 60 hours per year keeping and maintaining records showing their compliance with the suspension or exclusion orders. It is estimated that it takes 2 hours to report a complaint and that it takes 5 minutes (0.08 hours) to 4 hours to respond to a complaint and provide other information as necessary. The estimated times will vary, depending upon the request. These estimates include the time to gather the necessary information, prepare the complaint, response or request, to maintain records, and to submit the requests or responses to the USPTO.

Estimated Total Annual Respondent Burden Hours: 8,334 hours per year.

Estimated Total Annual Respondent Cost Burden: $388,864 per year. Using the professional hourly rate of $252 per hour for associate attorneys in private firms, and the hourly rate of $30 for a para-professional/clerical worker, the USPTO estimates $355,464 per year for salary costs associated with respondents for all of the information and recordkeeping requirements in this collection, with the exception of the complaint/violation reporting. The USPTO predicts that half of the complaints will be filed by practitioners and that the remaining complaints will be split evenly between non-legal/professionals and semi-professionals or skilled trade. The USPTO estimates that it will cost practitioners $252 per hour, non-legal/professionals $156 per hour, and semi-professionals or skilled trade $60 per hour to submit a complaint, for a weighted average hourly rate of $180 per hour. Considering these factors, the USPTO estimates $36,000 per year for salary costs associated with filing a complaint, for a total annual respondent cost burden of $391,464 per year.

Item	Estimated time for response (hours)	Estimated annual responses	Estimated annual burden hours
Record Keeping Maintenance (including financial books and records such as trust accounts, fiduciary accounts, operating accounts, and advertisements)	26	282	7,332

Item	Estimated time for response (hours)	Estimated annual responses	Estimated annual burden hours
Record Keeping Maintenance Under Suspension or Exclusion from the USPTO	60	5	300
Complaint/Violation Reporting	2	100	200
Responses to Requests/Requirements for Information	3	150	450
Requests for Extension of Time to Respond	[1] 5	30	2
Responses to Settlement Offers	3	10	30
Responses to Show Cause	4	5	20
Total		582	8,334

[1] Minutes.

Estimated Total Annual Nonhour Respondent Cost Burden: $661. There are no capital start-up or maintenance costs associated with this information collection. However, there are postage costs associated with this collection.

The public may submit the complaints, responses, and requests in this collection to the USPTO by mail through the United States Postal Service. If these documents are sent by first-class mail, a certificate of mailing for each piece of correspondence, stating the date of deposit or transmission to the USPTO, may also be included.

The USPTO expects that the complaints will be mailed to the USPTO by first-class postage, for an average cost of 49 cents. The USPTO estimates that up to 100 responses may be mailed by first-class mail (49 cents), for a total postage cost of $49 per year.

The USPTO believes that the responses to requests/requirements for information and the responses to show cause will be mailed to the USPTO by first-class or priority mail. Since these submissions are frequently bulky in nature, the USPTO estimates that they could weigh up to one pound, for an average postage cost of $3.85. The USPTO estimates that up to 155 responses may be mailed by first-class or priority mail ($3.85), for a total postage cost of $597 per year.

The USPTO believes that the requests for extension of time to respond and the responses to settlement offers will be mailed to the USPTO by first-class postage, for an average cost of 37 cents. The USPTO estimates that up to 40 responses may be mailed by first-class mail (37 cents), for a total postage cost of $15 per year.

Therefore, this information collection has a total of $661 in postage costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they will also become a matter of public record.

Dated: May 21, 2003.

Susan K. Brown,

Records Officer, USPTO, Office of Data Architecture and Services, Data Administration Division.

[FR Doc. 03–13316 Filed 5–28–03; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF THE DEFENSE

Office of the Secretary

Notice of Availability for Public Viewing of the Draft Environmental Assessment for the Pulsed Fast Neutron Analysis Cargo Inspection System Test Facility at the Ysleta Port of Entry Commercial Cargo Facility, El Paso, TX

AGENCY: Counterdrug Technology Development Program Office (CTDPO), DoD.

ACTION: Notice of availability.

SUMMARY: The notice announces that a draft Environmental Assessment (EA) regarding potential environmental impacts resulting from the Pulsed Fast Neutron Analysis (PFNA) Cargo Inspection System Test Facility is available for public review. The facility will be constructed at the Ysleta Port of Entry cargo lot in El Paso, Texas. The Counterdrug Technology Development Program Office (CTDPO) will consider comments before issuing a final EA.

DATES: The draft EA will be available for public review for a 30-day period beginning on May 29, 2003. Written comments must be received by June 30, 2003.

ADDRESSES: Written comments may be submitted to the Department of Defense, Counterdrug Technology Development Program Office, Naval Surface Warfare Center, 17320 Dahlgren Road, Dahlgren, Virginia 22448–5100, Attn: Dr. Stephen Haimbach. Copies of the draft EA will be available for viewing at the above address. Copies may also be obtained by telephone request through the following phone number: 540/653–2374, and by accessing the following Internet address: *http://www.scainc.biz/EA*.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen Haimbach at 540/653–2374 or at *PFNAmail@dodcounterdrug.com.*

SUPPLEMENTARY INFORMATION:

Background

Introduction

In its counter-terrorism and counter-drug efforts, the Federal government has invested considerable resources into developing technologies for detecting explosives, narcotics or other contraband hidden among the freight imported into the United States. Radiation-based, non-intrusive inspections systems, such as X-ray and gamma ray, have been in use for several years by Federal government agencies. A related technology, called Pulsed Fast Neutron Analysis (PFNA), was developed several years ago for cargo inspection. PFNA is designed to directly and automatically detect and measure the presence of specific materials, such as cocaine or explosives, which may have been hidden within the vehicle. PFNA technology uses pulses of neutrons as the radiation source to non-intrusively examine packages and containers for suspect materials. While PFNA has been successfully demonstrated in a laboratory setting, it

has yet to be tested in an operational environment.

The Department of Defense (DoD) in cooperation with the United States Bureau of Customs and Border Protection and the Transportation Security Administration plans to conduct a six-month operational test of a PFNA system at the Ysleta/Zaragosa Border Station in Ysleta, Texas. Ysleta is next to the Rio Grande River just southeast of the city of El Paso. Ysleta was selected as the test location principally because it had space available (no additional land purchase was required) and sufficient commercial traffic.

The test facility will consist of an inspection building (approximately 220 feet by 60 feet) housing the PFNA equipment and several smaller structures for electronic equipment and operators.

Inspection Process

Vehicles will be selected for inspection from the routine stream of commerce and will be directed to the PFNA test facility. The driver will leave the vehicle and wait in a designated area. A self-powered towing machine will slowly pull the unoccupied vehicle through the facility and past the scanning device in the inspection building. Once all safety checks are verified, the vehicle is scanned with the neutrons. The pulsed beam moves up and down while the vehicle slowly passes by to ensure that all of the contents are inspected.

Many of the neutrons pass through the vehicle unaffected and are stopped by the shield walls of the inspection building. Some of the neutrons hit individual atoms, subsequently giving off a gamma ray of a specific frequency that is characteristic of a chemical element. Sensors located along the walls of the corridor detect the quantities for each of the specific frequencies of gamma rays for the short period of time of each pulse of neutrons. The system's electronics and computers compile the gamma ray information to determine the properties of individual material locations within the vehicle. For the chemical makeup of specific explosives and narcotics, the computers automatically alert operators of the presence of these substances. The PFNA system generates three-dimensional images of the target materials on computer monitors to help pinpoint the location of suspect materials for U.S. Customs inspectors.

Radiation Properties

While the neutron generator used in PFNA systems does not contain radioactive material, the neutron production process does produce a trace amount of radioactive material. Specifically, a small amount (less than 1/100th of the levels allowed by the EPA regulations) of the radioisotope tritium (radioactive hydrogen) is a byproduct of the process, which is vented to the atmosphere.

The neutrons produce radioactive isotopes of some of the atoms within the vehicle. This may increase the level of radioactivity of scanned cargo materials. Computer modeling has shown that the level of induced radioactivity is of little consequence to human health. Residual radioactivity measurements will be made during the test to confirm the absence of significant levels of radioactivity.

For safety, personnel are shielded from radiation by staying out of the equipment area during operations. The facility's walls are designed to prevent all but minute amounts of radiation from leaving the area. X-rays and gamma rays are produced both by the fast moving neutrons themselves as they collide with atoms, and the neutron producing equipment. X-rays and gamma rays are both forms of ionizing radiation, which by virtue of their high energy, can convert molecules into charged ions, and pose an increased risk of cancer with excessive exposure. Visible light, infrared light, microwaves, and radio waves are non-ionizing forms of electromagnetic radiation because of their relatively lower energies.

It is believed that the PFNA inspection system is safe, with exposures to radioactive materials and ionizing radiation to the general public and US Customs personnel well below Federal and State standards. The facility design, including radiation shielding, will be designed to ensure that levels of exposure will be statistically indistinguishable from local area background.

Public Review of the Draft Environmental Assessment

Pursuant to the National Environmental Policy Act (NEPA) and the Council on Environmental Quality regulations implementing NEPA (40 Code of Federal Regulations (CFR) Parts 1500–1508), the assessment has been conducted to determine whether the proposed action is a major federal action having significant effects on the environment, which would require preparation of an Environmental Impact Statement (EIS), or whether the impacts of the proposed action (after mitigation) are less than significant, which would result in preparation of a Finding of No Significant Impact (FONSI).

This notice announces a 30-day period for public review of the draft EA and a 30-day period for submitting comments to CTDPO, both periods commencing on the date this document is published in the **Federal Register.**

Evaluation of Environmental Impact

Significant comments received from the public and agencies during the comment period will be addressed in, and included as an Appendix to, the final EA. Notice of issuance of the final EA will be published in the **Federal Register.**

Should CTDPO determine, based on comments received and any additional relevant information developed, that the design, construction, and/or operation of PFNA system will not have a significant impact on the environment, CTDPO will prepare a FONSI, notice of which will be published in the **Federal Register.** Should CTDPO determine that significant environmental impacts exist due to the project, CTDPO will proceed with preparation of an EIS as required under the NEPA, the CEQ Regulations (40 CFR part 1502), and the Department of Defense's environmental policies and procedures.

Public Review and Comments

The draft EA will be available for public review for a period of 30 days beginning on the date this document is published in the **Federal Register.** The draft EA can be reviewed at the following address: Ysleta Branch of the El Paso Public Library, 9321 Alameda Ave., El Paso, Texas 79907. Printed copies of the draft EA are $50.00 each and may be obtained by telephone request through the following phone number: 410/593–9909, or freely downloaded by accessing the following Internet address: *www.scainc.biz/EA.*

Comments regarding the draft EA may be submitted as set forth in the **ADDRESSES** section of this document.

Dated: May 23, 2003.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 03–13516 Filed 5–27–03; 10:44 am]

BILLING CODE 5001–08–P

DEPARTMENT OF EDUCATION

Direct Grant Programs

AGENCY: Department of Education.

ACTION: Notice reopening application deadline dates for certain direct grants.

SUMMARY: The Secretary reopens the deadline dates for the submission of applications from applicants in certain

nationally declared disaster areas for two competitions. Both of the affected competitions are among those under which the Secretary is making new awards for fiscal year (FY) 2003. The Secretary takes this action to allow more time for the preparation and submission of applications by potential applicants who have been affected by severe weather conditions in certain States. The reopening of these deadline dates is intended to help the potential applicants compete fairly with other applicants under these competitions.

Note: The affected competitions are under the following principal offices of the Department: Office of Elementary and Secondary Education and Office of Safe and Drug-Free Schools. You can find specific information related to the affected competitions in the chart published as an Appendix to this notice.

Eligibility: The reopening of deadline dates in this notice applies to you if you are a potential applicant from an area on the following chart. The President has declared each of these locations a disaster area as a result of recent severe weather conditions. These areas are as follows:

State	County
Alabama	Bibb, Blount, Calhoun, Cullman, DeKalb, Etowah, Jackson, Jefferson, Madison, Marshall, Morgan, Shelby, St. Clair, Talladega, Tuscaloosa, Walker.
Illinois	Adams, Alexander, Brown, Fulton, Hancock, Mason, Massac, Pope, Pulaski, Schuyler, Tazewell, Woodford.
Kansas	Anderson, Cherokee, Crawford, Douglas, Labette, Leavenworth, Miami, Neosho, Osage, Woodson, Wyandette.
Missouri	Barry, Barton, Bates, Benton, Buchanan, Camden, Cass, Cedar, Christian, Clay, Clinton, Cooper, Dade, Dallas, Douglas, Greene, Henry, Hickory, Jackson, Jasper, Johnson, Laclede, Lafayette, Lawrence, McDonald, Miller, Morgan, Newton, Pettis, Platte, Polk, Pulaski, Ray, Saline, St. Clair, Stone, Taney, Vernon, Webster.
Oklahoma	Canadian, Cleveland, Grady, Kingfisher, Lincoln, Logan, McClain, Oklahoma, Pottawatomie.
Tennessee	Carroll, Cheatham, Chester, Crockett, Dickson, Dyer, Gibson, Hardeman, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, Madison, Montgomery, Obion, Robertson, Stewart, Weakley.

DATES: The new deadline date for transmitting applications under each competition is listed with that competition in the chart published as an Appendix to this notice.

If the program in which you are interested is subject to Executive Order 12372, the deadline date for the transmittal of State process recommendations by State Single Points of Contact (SPOCs) and comments by other interested parties remains as originally published.

ADDRESSES: The address and telephone number for obtaining applications for, or information about, an individual program are in the application notice for that program. We have listed the date and **Federal Register** citation of the application notice for each program.

If you use a telecommunications device for the deaf (TDD), you may call the TDD number, if any, listed in the individual application notice. If we have not listed a TDD number, you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

If you want to transmit a recommendation or comment under Executive Order 12372, you can find the latest list and addresses of individual SPOCs on the Web site of the Office of Management and Budget at the following address: *http://www.whitehouse.gov/omb/grants.*

If you are an individual with a disability, you may obtain a copy of this notice in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the individual application notices.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/legislation/FedRegister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html.*

Dated: May 22, 2003.

Jack Martin,

Chief Financial Officer.

APPENDIX.—LIST OF COMPETITIONS COVERED BY THIS NOTICE

CFDA No. and Name	Publication date and Federal Register cite	Original deadline date for applications	Revised deadline date for applications
Office of Elementary and Secondary Education: 84.349A Early Childhood Educator Professional Development Program.	3/31/03 (68 FR 15644)	5/16/03	5/30/03
Office of Safe and Drug-Free Schools: 84.215F Carol M. White Physical Education Program.	4/1/03 (68 FR 15911)	5/12/03	6/6/03

[FR Doc. 03–13462 Filed 5–28–03; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No.: 84.351C]

Office of Innovation and Improvement—Professional Development for Arts Educators; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2003; Correction

On May 16, 2003, a notice inviting applications for new awards for Professional Development for Arts Educators was published in the **Federal Register** (68 FR 26951). On page 26954, second column, first line, the telephone number is corrected to read ''(202) 260–1990.''

FOR FURTHER INFORMATION CONTACT: Lynyetta Johnson, U.S. Department of Education, 400 Maryland Avenue, SW., room 3E206 FB–6, Washington, DC 20202–6140. Telephone: (202) 260–1990 or via Internet: *lynyetta.johnson@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT.**

Electronic Access To This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/legislation/FedRegister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498, or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html.*

Program Authority: 20 U.S.C. 7271.

Dated: May 23, 2003.

Nina Rees,

Deputy Under Secretary for Innovation and Improvement.

[FR Doc. 03–13463 Filed 5–28–03; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA Nos.: 84.133B–1, 84.133B–5, 84.133B–7]

Office of Special Education and Rehabilitative Services.

National Institute on Disability and Rehabilitation Research—Rehabilitation Research and Training Centers (RRTC) Program; Notice inviting applications for fiscal year (FY) 2003.

Purpose of the Program: The purpose of the RRTC program is to improve the effectiveness of services authorized under the Rehabilitation Act of 1973 (the Act), as amended. We intend these priorities to improve the rehabilitation services and outcomes for individuals with disabilities.

In order to provide applicants with a 60-day application period and to ensure that these grants are awarded before the end of FY 2003, the National Institute on Disability and Rehabilitation Research (NIDRR) is inviting applications based on the proposed priorities. NIDRR will publish the final priorities after the comment period closes on June 9, 2003.

Depending upon the comments that NIDRR receives, the final priorities may include revisions to the proposed priorities. It is generally the policy of the Department of Education not to solicit applications before the publication of a final priority. However, in this case, it is essential to solicit applications on the basis of these proposed priorities in order to allow applicants sufficient time to prepare applications of appropriate quality to be funded. Applicants are advised to begin to develop their applications based on the proposed priorities. If changes are made in the final priorities, applicants will be given an opportunity to revise or resubmit their applications.

Eligible Applicants: Parties eligible to apply for grants under this program are States; public or private agencies, including for-profit agencies; public or private organizations, including for-profit organizations; institutions of higher education; and Indian tribes and tribal organizations.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR), 34 CFR parts 74, 75, 77, 80, 81, 82, 85, 86, and 97, and (b) The program regulations 34 CFR part 350.

Indirect Cost Rate: An applicant for an RRTC is limited to an indirect rate of 15 percent.

Letter of Intent: The due date for the Letter of Intent has been extended to June 18, 2003.

REHABILITATION RESEARCH AND TRAINING CENTERS (84.133B)

[Applications for FY 2003]

CFDA No./program name	Application available	Deadline for transmittal of applications	Estimated available funds	Maximum award amount (per year)*	Estimated number of awards**	Project period (months)
84.133B–1 Disability Demographics and Statistics.	May 29, 2003	July 28, 2003	$750,000	$750,000	1	60
84.133B–5 Community Integration Outcomes.	May 29, 2003	July 28, 2003	2,400,000	600,000	4	60
84.133B–7 Health and Function.	May 29, 2003	July 28, 2003	200,000	600,000	7	60

* **Note:** We will reject without consideration any application that proposes a budget exceeding the stated maximum award amount in any year (*See* 34 CFR 75.104(b)).

** The Department is not bound by any estimates in this notice.

Priorities

This competition focuses on projects designed to meet the priorities in the notice of proposed priorities for the programs published in the **Federal Register** on May 9, 2003. (**Note:** See individual priority for **Federal Register** cite.) Under 34 CFR 75.105 (c)(3) we consider only applications that meet one or more of the following priorities. A separate application is required for each priority area.

Absolute Priority 1—Disability Demographics and Statistics Center (84.133B–1) (68 FR 25004)

Absolute Priority 2—Community Integration Outcomes Centers (84.133B–5) (68 FR 25019)

Absolute Priority 3—Health and Function Centers (84.133B–7) (68 FR 25011)

Selection Criteria

The selection criteria to evaluate applications under these priorities are included in the application package.

For Applications Contact: Education Publications Center (ED Pubs), PO Box 1398, Jessup, MD 20794–1398. Telephone (toll free): 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1–877–576–7734.

You may also contact ED Pubs at its Web site: *http://www.ed.gov/pubs/edpubs.html*, or you may contact ED Pubs at its e-mail address: *edpubs@inet.ed.gov*.

If you request an application from ED Pubs, be sure to identify these competitions as follows: CFDA number 84.133B–1, 84.133B–5, or 84.133B–7.

Application Procedures

NOTE: Some of the procedures in these instructions for transmitting applications differ from those in the 34 CFR 75.102. Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed regulations. However, these amendments make procedural changes only and do not establish new substantive policy. Therefore, under 5 U.S.C. 553(b)(A), the Secretary has determined that proposed rulemaking is not required.

Pilot Project for Electronic Submission of Applications

In FY 2003, the U.S. Department of Education is continuing to expand its pilot project for electronic submission of applications to include additional formula grant programs and additional discretionary grant competitions. The Rehabilitation Research and Training Centers (RRTC) program—CFDA #84.133B is one of the programs included in the pilot project. If you are an applicant under the RRTC program, you may submit your application to us in either electronic or paper format.

The pilot project involves the use of the Electronic Grant Application System (e-Application) portion of the Grant Administration and Payment System (GAPS). Users of e-Application will be entering data on-line while completing their applications. You may not e-mail a soft copy of a grant application to us. If you participate in this voluntary pilot project by submitting an application electronically, the data you enter on-line will be saved into a database. We request your participation in e-Application. We shall continue to evaluate its success and solicit suggestions for improvement.

If you participate in e-Application, please note the following:

- Your participation is voluntary.
- You will not receive any additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format. When you enter the e-Application system, you will find information about its hours of operation.
- You may submit all documents electronically, including the Application for Federal Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- After you electronically submit your application, you will receive an automatic acknowledgement, which will include a PR/Award number (an identifying number unique to your application).
- Within three working days after submitting your electronic application, fax a signed copy of the Application for Federal Assistance (ED 424) to the Application Control Center after following these steps:

(1) Print ED 424 from the e-Application system.

(2) The institution's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard copy signature page of the ED 424.

(4) Fax the signed ED 424 to the Application Control Center at (202) 260–1349.

- We may request that you give us original signatures on all other forms at a later date.
- *Closing Date Extension in Case of System Unavailability:* If you elect to participate in the e-Application pilot for the RRTC program and you are prevented from submitting your application on the closing date because the e-Application system is unavailable, we will grant you an extension of one business day in order to transmit your application electronically, by mail, or by hand delivery. For us to grant this extension—

(1) You must be a registered user of e-Application, and have initiated an e-Application for this competition; and

(2)(a) The e-Application system must be unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the deadline date; or

(b) The e-Application system must be unavailable for any period of time during the last hour of operation (that is, for any period of time between 3:30 and 4:30 p.m., Washington, DC time) on the deadline date. The Department must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension you must contact either (1) the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT** or (2) the e-GRANTS help desk at 1–888–336–8930.

You may access the electronic grant application for the RRTC program at: *http://e-grants.ed.gov*.

We have included additional information about the e-Application pilot project (*see* Parity Guidelines between Paper and Electronic Applications) in the application package.

Pre-Application Meeting: Interested parties are invited to participate in a pre-application meeting to discuss the funding priorities and to receive information and technical assistance through individual consultation about the funding priorities. The pre-application meeting will be held on June 27, 2003 either in person or by conference call at the Department of Education, Office of Special Education and Rehabilitative Services, Switzer Building, room 3065, 330 C Street, SW., Washington, DC between 10 a.m. and 12 noon. NIDRR staff will also be available from 1:30 p.m. to 4 p.m. on that same day to provide information and technical assistance through individual consultation about the funding priority. For further information or to make arrangements to attend contact Donna Nangle, Switzer Building, room 3412, 330 C Street, SW., Washington, DC 20202. Telephone (202) 205–5880 or via Internet: *donna.nangle@ed.gov*.

If you use a telecommunications device for the deaf (TDD), you may call (202) 205–4475.

Assistance to Individuals With Disabilities at the Public Meetings

The meeting site is accessible to individuals with disabilities, and a sign language interpreter will be available. If you will need an auxiliary aid or service other than a sign language interpreter in order to participate in the meeting (*e.g.*, other interpreting service such as oral, cued speech, or tactile interpreter; assistive listening device; or materials in alternate format), notify the contact person listed in this notice at least two weeks before the scheduled meeting date. Although we will attempt to meet a request we receive after this date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

FOR FURTHER INFORMATION CONTACT: Donna Nangle, U.S. Department of Education, 400 Maryland Avenue, SW., room 3412, Switzer Building, Washington, DC 20202–2645.

Telephone: (202) 205–5880 or via Internet: *Donna.Nangle@ed.gov*.

If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 205–4475.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT.**

Electronic Access to this Document

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To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html*.

Program Authority: 29 U.S.C. 762(g) and 764(b)(2).

Dated: May 23, 2003.

Robert H. Pasternack,

Assistant Secretary for Special Education and, Rehabilitative Services.

[FR Doc. 03–13395 Filed 5–28–03; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services.

AGENCY: Office of Special Education Programs, Department of Education.

ACTION: Notice of extension of project period and waiver.

SUMMARY: The Secretary waives the requirements in the Education Department General Administrative Regulations (EDGAR), at 34 CFR 75.250 and 75.261(a), respectively, that generally prohibit project periods exceeding 5 years and project extensions involving the obligation of additional Federal funds to enable the currently-funded Regional Resource Centers (RRCs) to receive funding from June 1, 2003 until May 31, 2004.

DATES: This notice is effective June 1, 2003.

FOR FURTHER INFORMATION CONTACT: Marie Roane, U.S. Department of Education, 400 Maryland Avenue, SW., room 3611, Switzer Building, Washington, DC 20202–2641. Telephone: (202) 205–8451.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact persons listed under **FOR FURTHER INFORMATION CONTACT.**

SUPPLEMENTARY INFORMATION:

Invitation to Comment

On March 31, 2003, we published a notice in the **Federal Register** (68 FR 15439–15440) proposing an extension of project period and waiver in order to—

(1) Give the current grantees early notice of the possibility that additional months of funding may be available through continuation awards; and

(2) Request comments on the proposed extension and waiver.

There are no differences between the notice of proposed extension and waiver and this notice of final extension and waiver.

Analysis of Comments and Changes

In response to the Assistant Secretary's invitation in the notice of proposed extension and waiver, three parties submitted comments. One party submitted comments in agreement with the proposal to extend the grant period of the current grantees. Two parties submitted comments opposing the proposed extension and waiver. Generally, we do not address technical and other minor changes, as well as suggested changes the law does not authorize us to make. Moreover, we do not address comments that do not express views on the substance of the proposed notice.

An analysis of the parties' comments opposing the proposed extension and waiver and our response follows.

Comment: One commenter stated that funding should be cut for the RRCs rather than waive the EDGAR requirement for a project period extension. The commenter further stated that it is more important to get services to children with disabilities and States than it is to have another intermediate intervening system.

Discussion: The existing RRCs are currently involved in carrying out activities related to the Office of Special Education Programs initiative to identify and disseminate alternative approaches to identifying children with disabilities. The Secretary believes that this is an important endeavor and the current RRCs have already conducted extensive training and information activities related to State implementation of IDEA and they are best suited to assist in efforts to provide or gather information related to the activities described in this notice.

Change: None.

Comment: One commenter stated that the proposed extension and waiver should not be approved. The commenter further stated that by granting the proposed extension and waiver, it curtails the current competitive system, and serves to reward current grantees without consideration of potential grantees that might better provide for current needs.

Discussion: The Secretary has determined that there is a critical need in the States for identifying and disseminating alternative approaches to identify children with learning disabilities. Waiting until after a new RRC competition would hinder the efforts that are in place. The Secretary believes that by providing continuous support to the existing grantees will avoid the disruption of activities that are currently taking place in the regions to address these needs.

Change: None.

Background

On February 24, 1998, we published in the **Federal Register** (63 FR 9376–9378) a notice inviting applications for new awards under the Regional Resource Center Program for fiscal year 1998. Based on this notice, the Department made six awards of 56 months under 34 CFR 75.105(c)(3) and the Individuals with Disabilities Education Act (IDEA). Section 685 of IDEA authorizes the Secretary to support the establishment of Regional Resource Centers (RRCs). These Centers provide technical assistance and information that support States and local agencies in building capacity to improve early intervention, educational, and transitional services and results for children with disabilities and their families, and address systemic-change goals and priorities. The grant period for the six centers ends May 31, 2003.

In order to carry out activities related to implementing an initiative of the Office of Special Education Programs (OSEP) to identify and disseminate alternative approaches to identifying children with learning disabilities, it is necessary to issue continuation awards to the existing grantees. Specifically, the current RRCs are helping to conduct a survey in each of their regions to collect information on the ways that States identify children with learning disabilities.

In particular, the Secretary plans for the RRCs to work with staff of OSEP, the Kennedy Center Research Program on Learning Accommodations for Individuals with Special Needs at Vanderbilt University, State educational agencies, regional in-state technical assistance systems and other State and local agencies to:

(1) Develop a coordinated plan for identifying sites within each RRC region using alternative approaches for identification of children with learning disabilities;

(2) Assist in efforts to provide or gather evidence of the value of more effective approaches for addressing the needs of children with learning disabilities; and

(3) Use research-based dissemination, training, and technical assistance to extend and increase effective practices in the area of learning disabilities.

The RRCs will also work with centers providing technical assistance to projects funded under the Training and Information for Parents of Children with Disabilities program to continue to foster improved collaboration on the No Child Left Behind Act of 2001 and IDEA, which will improve results for children with disabilities.

In addition, the Secretary plans for the RRCs to provide continued assistance to State educational agencies for Part B and the lead agencies for Part C in each region to support their implementation of continuous improvement and focused monitoring activities.

Reasons for Extension and Waiver

There is an immediate need to provide training and information to the populations that will be targeted by these efforts. Providing continuous support to existing grantees will help ensure the success of these efforts by avoiding the possible disruption or interruption of activities resulting from a change in grantees. Waiting until after a new RRC competition to begin this important work would severely hinder the Department's efforts to address the critical needs that are now present in the regions. The current RRCs have already conducted extensive training and information activities related to State implementation of the IDEA Amendments of 1997 and are best suited to conduct this effort. We have determined that an additional period of time is needed to begin the additional technical assistance and training activities described in this notice.

Therefore, the Secretary will issue continuation awards to the current grantees for twelve (12) months. A one-year time extension beginning June 1, 2003 thru May 31, 2004 is allowed to ensure the successful completion of the projects. The Secretary waives the requirements in 34 CFR 75.250 and 75.261(c)(2), which prohibit project periods exceeding 5 years and extensions that involve the obligation of additional Federal funds. This waiver gives the affected grantees early notice of the availability of an additional twelve months of funding.

Regulatory Flexibility Act Certification

The Secretary certifies that the extension of project period and waiver will not have a significant economic impact on a substantial number of small entities. The only small entities that would be directly affected are the six RRCs.

Paperwork Reduction Act of 1995

This extension of project period and waiver does not contain any information collection requirements.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/legislation/FedRegister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html.*

(Catalog of Federal Domestic Assistance Number 84.326, Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities.)

Dated: May 23, 2003.

Robert H. Pasternack,

Assistant Secretary for Special Education and, Rehabilitative Services.

[FR Doc. 03–13396 Filed 5–28–03; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services

[CFDA Nos.: 84.133A–1, 84.133A–4, 84.133A–5, 84.133A–7]

National Institute on Disability and Rehabilitation Research—Disability Rehabilitation Research Projects (DRRP) Program

Notice inviting applications for fiscal year (FY) 2003.

Purpose of the Program: The purpose of the DRRP program is to improve the effectiveness of services authorized under the Rehabilitation Act of 1973 (the Act), as amended. For FY 2003 the competitions for new awards focus on projects designed to meet the priorities we describe in the Priority section of this application notice. We intend these

priorities to improve rehabilitation services and outcomes for individuals with disabilities.

In order to provide applicants with a 60-day application period and to ensure that these grants are awarded before the end of FY 2003, the National Institute on Disability and Rehabilitation Research (NIDRR) is inviting applications based on the proposed priorities. NIDRR will publish the final priorities as soon as possible after the comment period closes on June 9, 2003.

Depending upon the comments that NIDRR receives, the final priorities may include revisions to the proposed priorities. It is generally the policy of the Department of Education not to solicit applications before the publication of a final priority. However, in this case, it is essential to solicit applications on the basis of these proposed priorities in order to allow applicants sufficient time to prepare applications of appropriate quality to be funded. Applicants are advised to begin to develop their applications based on the proposed priorities. If changes are made in the final priorities, applicants will be given an opportunity to revise or resubmit their applications.

Eligible Applicants: Parties eligible to apply for grants under this program are States; public or private agencies, including for-profit agencies; public or private organizations, including for-profit organizations; institutions of higher education; and Indian tribes and tribal organizations.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR), 34 CFR parts 74, 75, 77, 80, 81, 82, 85, 86, and 97, and (b) The program regulations 34 CFR part 350.

Letter of Intent: The due date for the Letter of Intent has been extended to June 18, 2003.

DISABILITY AND REHABILITATION RESEARCH PROJECTS (84.133A)

[Applications for FY 2003]

CFDA No./Program name	Application available	Deadline for transmittal of applications	Estimated available funds	Maximum award amount (per year) [1]	Estimated number of awards [2]	Project period (months)
84.133A–1 Research Projects	May 29, 2003	July 28, 2003	$600,000	$300,000	2	60
84.133A–4 Research Infrastructure Capacity Building.	May 29, 2003	July 28, 2003	600,000	600,000	1	60
84.133A–5 Technical Assistance Resource Center on Parenting with a Disability.	May 29, 2003	July 28, 2003	500,000	500,000	1	60
84.133A–7 Development Projects.	May 29, 2003	July 28, 2003	300,000	300,000	1	60

[1] **Note:** We will reject without consideration any application that proposes a budget exceeding the stated maximum award amount in any year (*See* 34 CFR 75.104(b)).

[2] The Department is not bound by any estimates in this notice.

Priorities

This competition focuses on projects designed to meet the priorities in the notice of proposed priorities for the programs published in the **Federal Register** on May 9, 2003. (**Note:** *See* individual priority for **Federal Register** cite.) Under 34 CFR 75.105(c)(3) we consider only applications that meet one or more of the following priorities. A separate application is required for each priority area.

Absolute Priority 1—Research Projects (84.133A–1) (68 FR 25014).

Absolute Priority 2—Research Infrastructure Capacity Building (84.133A–4) (68 FR 25009).

Absolute Priority 3—Technical Assistance Resource Center on Parenting with a Disability (84.133A–5) (68 FR 25017).

Absolute Priority 4—Development Projects (84.133A–7) (68 FR 25006).

Selection Criteria

The selection criteria to evaluate applications under these priorities are found in the application package.

For Applications Contact: Education Publications Center (ED Pubs), PO Box 1398, Jessup, MD 20794–1398. Telephone (toll free): 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1–877–576–7734.

You may also contact ED Pubs at its Web site: *http://www.ed.gov/pubs/edpubs.html.* Or you may contact ED Pubs at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify these competitions as follows: CFDA number 84.133A–1, 84.133A–4, 84.133A–5, and 84.133A–7.

Application Procedures

Note: Some of the procedures in these instructions for transmitting applications differ from those in the 34 CFR 75.102. Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed regulations. However, these amendments make procedural changes only and do not establish new substantive policy. Therefore, under 5 U.S.C. 553(b)(A), the Secretary has determined that proposed rulemaking is not required.

Pilot Project for Electronic Submission of Applications

In FY 2003, the U.S. Department of Education is continuing to expand its pilot project for electronic submission of applications to include additional formula grant programs and additional discretionary grant competitions. The Disability Rehabilitation Research Projects (DRRP) program—CFDA #84.133A is one of the programs included in the pilot project. If you are an applicant under the DRRP, you may submit your application to us in either electronic or paper format.

The pilot project involves the use of the Electronic Grant Application System (e-Application) portion of the Grant Administration and Payment System (GAPS). Users of e-Application will be entering data on-line while completing their applications. You may not e-mail a soft copy of a grant application to us. If you participate in this voluntary pilot project by submitting an application electronically, the data you enter on-line will be saved into a database. We request your participation in e-Application. We shall continue to evaluate its success and solicit suggestions for improvement.

If you participate in e-Application, please note the following:

- Your participation is voluntary.
- You will not receive any additional point value because you submit a grant

application in electronic format, nor will we penalize you if you submit an application in paper format. When you enter the e-Application system, you will find information about its hours of operation.

• You may submit all documents electronically, including the Application for Federal Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

• After you electronically submit your application, you will receive an automatic acknowledgement, which will include a PR/Award number (an identifying number unique to your application).

• Within three working days after submitting your electronic application, fax a signed copy of the Application for Federal Assistance (ED 424) to the Application Control Center after following these steps:

(1) Print ED 424 from the e-Application system.

(2) The institution's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard copy signature page of the ED 424.

(4) Fax the signed ED 424 to the Application Control Center at (202) 260–1349.

• We may request that you give us original signatures on all other forms at a later date.

• *Closing Date Extension in Case of System Unavailability:* If you elect to participate in the e-Application pilot for the DRRP and you are prevented from submitting your application on the closing date because the e-Application system is unavailable, we will grant you an extension of one business day in order to transmit your application electronically, by mail, or by hand delivery. For us to grant this extension—

(1) You must be a registered user of e-Application, and have initiated an e-Application for this competition; and

(2)(a) The e-Application system must be unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the deadline date; or

(b) The e-Application system must be unavailable for any period of time during the last hour of operation (that is, for any period of time between 3:30 and 4:30 p.m., Washington, DC time) on the deadline date. The Department must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension you must contact either (1) the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT** or (2) the e-GRANTS help desk at 1–888–336–8930.

You may access the electronic grant application for the DRRP at: *http://e-grants.ed.gov.*

We have included additional information about the e-Application pilot project (*see* Parity Guidelines between Paper and Electronic Applications) in the application package.

FOR FURTHER INFORMATION CONTACT: Donna Nangle, U.S. Department of Education, 400 Maryland Avenue, SW., room 3412, Switzer Building, Washington, DC 20202–2645. Telephone: (202) 205–5880 or via Internet: *Donna.Nangle@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 205–4475.

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Program Authority: 29 U.S.C. 762(g) and 764(a).

Dated: May 23, 2003.

Robert H. Pasternack,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 03–13458 Filed 5–28–03; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Brown v. Board of Education 50th Anniversary Commission; Meeting

AGENCY: Brown v. Board of Education 50th Anniversary Commission, Department of Education (ED).

ACTION: Notice of meeting.

SUMMARY: This notice provides the schedule of a forthcoming meeting of the Brown v. Board of Education 50th Anniversary Commission. This notice also describes the functions of the commission. This document is intended to notify the general public of their opportunity to attend.

DATE AND TIME: June 4, 2003, at 8:45 a.m.

ADDRESSES: Adams Mark Hotel, 1200 Hampton Street, Columbia, South Carolina, (803) 771–7000.

FOR FURTHER INFORMATION CONTACT: Gwendolen Long, Program Support Assistant, 330 C Street SW., Washington, DC 20202, (202) 205–9610.

SUPPLEMENTARY INFORMATION: The Brown v. Board of Education 50th Anniversary Commission is established under Public Law 107–41 to commemorate the 50th anniversary of the Brown decision. The Commission, in conjunction with the U.S. Department of Education, is responsible for planning and coordinating public education activities and initiatives. Also, the Commission, in cooperation with the Brown Foundation for Educational Equity, Excellence, and Research in Topeka, Kansas, and such other public or private entities as the Commission deems appropriate, is responsible for encouraging, planning, developing, and coordinating observances of the anniversary of the Brown decision. The meeting of the Commission is open to the public. Individuals who will need accommodations for a disability in order to attend the meeting (i.e., interpreting services, assistive listening devices, materials in alternative format) should notify Gwendolen Long at (202) 205–9556 by no later than May 30, 2003. We will attempt to meet requests after that date, but cannot guarantee availability.

Dated: May 22, 2003.

Gerald A. Reynolds,

Assistant Secretary for Civil Rights.

[FR Doc. 03–13372 Filed 5–28–03; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–301–077]

ANR Pipeline Company; Notice of Amended Negotiated Rate Filing

May 21, 2003.

Take notice that on May 16, 2003, ANR Pipeline Company (ANR),

tendered for filing three amended FTS–1 Agreements between ANR and NJR Energy Services containing corrected commencement dates. ANR advises that there are no other changes to the negotiated rate arrangement previously filed on May 1, 2003. ANR requests that the Commission accept and approve the negotiated rate arrangement to be effective May 1, 2003.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: May 28, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13307 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–200–102]

CenterPoint Energy Gas Transmission Company; Notice of Negotiated Rates

May 21, 2003.

Take notice that on May 16, 2003, CenterPoint Energy Gas Transmission Company (CEGT) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following tariff sheets to be effective May 16, 2003:

First Revised Sheet No. 861.
Second Revised Sheet No. 862.

CEGT states that the purpose of this filing is to reflect implementation of new negotiated rate transactions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: May 28, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13303 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–389–086]

Columbia Gulf Transmission Company; Notice of Negotiated Rate Filing

May 21, 2003.

Take notice that on May 13, 2003, Columbia Gulf Transmission Company (Columbia Gulf) tendered for filing the following contract for disclosure of a negotiated rate transaction:

First Amendment to Service Agreement No. 75267 between Columbia Gulf Transmission Company and FPL Energy Power Marketing, Inc., Dated March 21, 2003, as amended May 7, 2003.

In addition, Columbia Gulf request as part of its filing, FERC Gas Tariff, Second Revised Volume No. 1, Eleventh Revised Sheet No. 316, a proposed effective date of May 15, 2003.

Columbia Gulf states that it has served copies of the filing on all parties identified on the official service list in Docket No. RP96–389.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: May 27, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13305 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–422–005]

Kern River Gas Transmission Company; Notice of Compliance Filing

May 21, 2003.

Take notice that on May 14, 2003, Kern River Gas Transmission Company (Kern River) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, 1st Revised Sixth Revised Sheet No. 5-A, to be effective May 1, 2003. Kern River states that the purpose of this filing is to comply with

the Commission's April 30, 2003 order in Docket No. CP01–422–004.

Kern River indicates that it is revising the initial incremental rates for its 2003 Expansion Project that are proposed to become effective on May 1, 2003, to reflect the long-term financing of the 2003 Expansion Project.

Kern River states that it has served a copy of this filing upon its customers, interested state regulatory commissions, and intervenors on the official service list for Docket No. CP 01–422.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: May 27, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13290 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–315–001]

Kern River Gas Transmission Company; Notice of Compliance Filing

May 21, 2003.

Take notice that on May 15, 2003, Kern River Gas Transmission Company (Kern River) tendered for filing a compliance filing in response to the ''Order Accepting and Suspending Tariff Sheets Subject to Refund and Conditions and Further Review,'' dated April 30, 2003, in Docket No. RP03–315, pertaining to Kern River's proposed revisions to its pooling provisions.

Kern River states that it has served a copy of this filing upon each person designated on the official service list compiled by the Secretary in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: May 27, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13298 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–297–001]

MIGC, Inc.; Notice of Compliance Filing

May 21, 2003.

Take notice that on May 16, 2003, MIGC, Inc. (MIGC) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No.1, Substitute Original Sheet No. 90H; and Substitute Second Revised Sheet No. 66A, to become effective May 1, 2003.

MIGC states that the purpose of this filing is to comply with the Letter Order issued by FERC in the instant proceeding. On March 6, 2003, MIGC filed revised tariff sheets to implement new tariff provisions and clarify certain existing provisions. On April 30, 2003 a Letter Order was issued in this proceeding accepting the proposed tariff sheets effective May 1, 2003, subject to certain conditions discussed in the Order. The Commission directed MIGC to file necessary compliance revisions within 21 days of the date of the Order. MIGC indicates that this compliance filing includes the additional tariff revisions necessary.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: May 28, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13297 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–393–001]

Northern Natural Gas Company; Notice of Compliance Filing

May 21, 2003.

Take notice that on May 16, 2003, Northern Natural Gas Company (Northern) tendered for filing to become part of Northern's FERC Gas Tariff, Fifth Revised Volume No. 1 the following tariff sheets to be effective June 1, 2003:

Substitute Fifteenth Revised Sheet No. 61.
Substitute Fifteenth Revised Sheet No. 62.
Substitute Fifteenth Revised Sheet No. 63.
Substitute Fifteenth Revised Sheet No. 64.

Northern states that the filing establishes the fuel and unaccounted for

percentages to be in effect June 1, 2003, based on actual data for the 12 month period ended March 31, 2003. The revised tariff sheets are being filed to correct an inadvertent error in the calculation of the MidContinent Mainline fuel percentage. The filing results in a reduction to the previously filed MidContinent Mainline fuel percentage.

Northern further states that copies of the filing have been mailed to each of its customers and interested State Commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations.

Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: May 28, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13299 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–479–000]

Panhandle Eastern Pipe Line Company; Notice of Tariff Filing

May 21, 2003.

Take notice that on May 16, 2003, Panhandle Eastern Pipe Line Company (Panhandle) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the revised tariff sheets listed on Appendix A attached to the filing, to be effective June 15, 2003.

Panhandle states that the purpose of this filing, made in accordance with the provisions of Section 154.204 of the Commission's Regulations, is to update Panhandle's tariff by removing or revising provisions that have expired, to update certain provisions and to make minor modifications and corrections.

Panhandle states that copies of this filing are being served on all affected customers and applicable state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: May 28, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13301 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission PG&E Gas Transmission, Northwest Corporation Docket No. RP03–70–002; Notice of Compliance Filing

May 21, 2003.

Take notice that on May 19, 2003, PG&E Gas Transmission, Northwest Corporation (GTN) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the tariff sheets attached to Appendix A to the filing, with an effective date of May 8, 2003.

GTN states that the tariff sheets are being filed to comply with the Commission's May 7, 2003 Order on Technical Conference and Denying Request for Rehearing and Stay in this proceeding.

GTN further states that a copy of this filing has been served upon its customers and interested state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: June 2, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13302 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL01–10–000 and EL01–10–001]

Puget Sound Energy, Inc. v. All Jurisdictional Sellers of Energy and/or Capacity at Wholesale Into Electric Energy and/or Capacity Markets in the Pacific Northwest, Including Parties to the Western Systems Power Pool Agreement; Notice Scheduling Oral Argument

May 21, 2003.

On September 24, 2001, the Presiding Administrative Law Judge issued

Recommendations and Proposed Findings of Fact in this proceeding.[1] The Transaction Finality Group has asked the Commission to provide for oral argument before the Commission regarding the legal, factual and policy issues raised in the proceeding.[2] Because oral argument will assist the Commission in its decision making in this case, oral argument will be held on June 2, 2003, from 10 a.m. to 12 noon in the Commission Meeting Room at 888 First Street, NE., Washington, DC 20426.

The refund claimants will be allotted a total of one hour to present their arguments, a portion of which may be reserved for rebuttal purposes. The parties opposed to refunds also will be allotted one hour to present their arguments. No later than May 29, 2003, the parties in this proceeding must notify the Commission of the number of representatives they wish to present and the manner in which they desire to allocate their allotted time. The parties must be prepared to address all aspects of this case, except as indicated in footnote 2 above. The parties participating in the oral argument should also be prepared to cite the specific record evidence which supports their arguments. Parties are reminded that new evidence cannot be introduced at oral argument. Parties are asked not to bring any visual aids for use at the oral argument.

A transcript of the oral argument will be available immediately from Ace Reporting Company (202–347–3700 or 1–800–336–6646) for a fee. A transcript will also be available for the public on the Commission's FERRIS system two weeks after the oral argument. Additionally, Capitol Connection offers the opportunity for remote listening and viewing of the oral argument. It is available for a fee, live over the Internet, via C-Band Satellite. Persons interested in receiving the broadcast or needing information on making arrangements should contact David Reininger or Julia Morelli at the Capitol Connection (703–993–3100) as soon as possible or visit the Capitol Connection Web site at *http://www.capitolconnection.gmu.edu* and click on ''FERC.''

Magalie R. Salas,

Secretary.

[FR Doc. 03–13291 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

[1] Puget Sound Energy, Inc. v. All Jurisdictional Sellers of Energy, *et al.*, 96 FERC ¶ 63,044 (2001).

[2] In a separate motion, Indicated Government Entities ask for oral argument on one discrete issue: whether the Commission can order governmental entities to make refunds for bilateral contract transactions in the Pacific Northwest markets. Argument on this issue will not be allowed.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–312–124]

Tennessee Gas Pipeline Company; Notice of Negotiated Rates

May 21, 2003.

Take notice that on May 16, 2003, Tennessee Gas Pipeline Company (Tennessee), tendered for filing its Negotiated Rate Tariff Filing.

Tennessee's filing requests that the Commission approve a negotiated rate arrangement between Tennessee and U.S. Gypsum Company. Tennessee requests that the Commission grant such approval effective October 16, 1996.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: May 28, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13304 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–478–000]

Texas Gas Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

May 21, 2003.

Take notice that on May 16, 2003, Texas Gas Transmission Corporation (Texas Gas) tendered for filing as part of its FERC Gas Tariff, the tariff sheets listed below to become effective May 16, 2003:

First Revised Volume No. 1.
First Revised Sheet No. 2A.
FPC Gas Tariff, Original Volume No. 2.
Tenth Revised Sheet No. 1.

In accordance with Section 154.602 of the Commission Regulations, Texas Gas files herewith a Notice of Cancellation for its FPC Tariff, Original Volume No. 2. Original Volume No. 2 had previously contained Texas Gas's X-Rate Schedules, which have subsequently all been cancelled or terminated. The proposed First Revised Sheet No. 2A sets forth the statement of cancellation and thereby removes all reference to Original Volume No. 2 from Texas Gas's FERC Gas Tariff, First Revised Volume No. 1.

Texas Gas states that copies of the tariff sheets are being mailed to all parties on Texas Gas's official service list, to Texas Gas's jurisdictional customers, and to interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at

FERCOnlineSupport@ferc.gov or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: May 28, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13300 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–479–003 and RP00–624–003]

Trailblazer Pipeline Company; Notice of Compliance Filing

May 21, 2003.

Take notice that on May 16, 2003, Trailblazer Pipeline Company (Trailblazer) tendered for filing to be a part of its FERC Gas Tariff, Third Revised Volume No. 1, the tariff sheets listed on Appendix A to the filing , some of which are to be effective May 1, 2003, and some of which are pro forma.

Trailblazer states that the purpose of this filing is to comply with the Commission's Order on Rehearing and Compliance Filing, issued in Docket Nos. RP00–479–000 and RP00–624–000, on April 16, 2003 (Order). The Order approved, subject to a number of modifications, Trailblazer's compliance filing related to its Order No. 637 docket filed herein on November 14, 2001.

Trailblazer states that copies of the filing have been mailed to all parties set out on the Commission's official service list in Docket Nos. RP00–479 and RP00–624.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: May 28, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13296 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–106–008]

TransColorado Gas Transmission Company; Notice of Revenue Report

May 21, 2003.

Take notice that on May 16, 2003, TransColorado Gas Transmission Company (TransColorado) tendered for filing its revenue sharing report in accordance with the provisions of the Settlement in Docket No. RP99–106 and the Commission's Order dated April 24, 2002.

TransColorado states that a copy of this filing has been served upon all parties listed on the official service list in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accrodance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866)208–3676, or TTY, contact (202)502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: May 29, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13306 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RM01–12–000 and EL02–101–000]

Remedying Undue Discrimination Through Open Access Transmission Service and Standard Electricity Market Design; Notice of Technical Conference

May 21, 2003.

Cleco Power LLC; Dalton Utilities (Acting as agent for the City of Dalton, Georgia); Entergy Services, Inc. (Acting as agent for Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy, Mississippi, Inc., and Entergy New Orleans, Inc.); Georgia Transmission Corporation; JEA (formerly Jacksonville Electric Authority); MEAG Power; Sam Rayburn G & T Electric Cooperative, Inc.; Southern Company Services, Inc. (Acting as agent for Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company, and Savannah Electric and Power Company); and the City of Tallahassee, Florida

1. Take notice that a technical conference will be held on June 5, 2003, from approximately 10 a.m. to 4 p.m. at the Atlanta Hilton Hotel, 255 Courtland NE., Atlanta, Georgia. Members of the Commission will attend and participate in the discussions. An agenda will be issued at a later time.

2. This conference is one in a series of regional technical conferences announced in the White Paper issued in Docket No. RM01–12–000 on April 28, 2003. The purpose of the conference is to discuss wholesale market platform and RTO issues. The Commission intends to use these conferences to discuss with states and market participants in each region reasonable timetables for addressing wholesale market design issues and to explore ways to provide the flexibility the region may need to meet the requirements of the final rule in this proceeding.

3. The conference is open for the public to attend, and registration is not

required; however, in-person attendees are asked to register for the conference on-line at *http://www.ferc.gov/home/conferences.asp*.

4. Transcripts of the conference will be immediately available from Ace Reporting Company (202–347–3700 or 1–800–336–6646) for a fee. They will be available for the public on the Commission's FERRIS system seven calendar days after FERC receives the transcript. Additionally, Capitol Connection offers the opportunity to remotely listen to the conference via the Internet or a Phone Bridge Connection for a fee. Interested persons should make arrangements as soon as possible by visiting the Capitol Connection Web site at http://www.capitolconnection.gmu.edu and clicking on ''FERC.'' If you have any questions contact David Reininger or Julia Morelli at the Capitol Connection (703–993–3100).

5. Questions about the conference program should be directed to: Steve Rodgers, Director, Division of Tariffs & Market Development—South, Office of Markets, Tariffs & Rates, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8227, steve.rodgers@ferc.gov.

Sarah McKinley, Manager of State Outreach, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8368, sarah.mckinley@ferc.gov.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13295 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No.2067–019]

Oakdale and South San Joaquin Irrigation Districts; Notice of Availability of Environmental Assessment

May 21, 2003.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects' staff has prepared an Environmental Assessment (EA) for an application requesting Commission approval to allow Merle and Beverly Holman use of project lands and waters to develop a commercial public access area located at the Tulloch Hydroelectric Project. The project is located on the Stanislaus River in Calaveras and Tuolumne Counties, California. The subject land does not involve federal or tribal lands.

The EA contains the staff's analysis of the potential environmental impacts of the proposal and concludes that approval of the proposal would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room, or it may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number (prefaced by P-) and excluding the last three digits, in the docket number field to access the document. For assistance, call contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202)502–8659.

For further information, contact Jean Potvin at 202–502–8928.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13292 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 2130–033, 2118–007, 2005–012, and 2067–020]

Notice of Intent To Prepare an Environmental Impact Statement and Notice of Scoping Meetings and Site Visit and Soliciting Scoping Comments

May 21, 2003.

Take notice that the following hydroelectric applications have been filed with Commission and are available for public inspection:

a. *Type of Applications:* New Major Licenses.

b. *Project Nos.:* 2130–033, 2118–007, 2005–012, and 2067–020.

c. *Dates filed*: P–2130 and P–2118 filed December 26, 2002; P–2005 and P–2067 filed December 23, 2002.

d. *Applicants:* Pacific Gas and Electric Company, current licensee for P–2130 and P–2118; and Tri-Dam Project, current licensee for P–2005 and P–2067.

e. *Name of Projects*: Spring Gap-Stanislaus Project No. 2130–033, Donnells-Curtis Transmission Line Project No. 2118–007, Beardsley/Donnells Project No. 2005–012, and Tulloch Project No. 2067–020.

f. *Location:* On the Middle Fork, South Fork, and mainstem of the Stanislaus River in Toulomne and Calaveras counties, California. All of the Beardsley/Donnells Project, most of the Spring Gap-Stanislaus Project, and all of the Donnell-Curtis Transmission Line Project are located within the Stanislaus National Forest.

g. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. §§ 791(a)—825(r).

h. *Applicant Contact:* Mr. Randy Livingston, Pacific Gas and Electric Company, PO Box 770000, Mail Code: N11C, San Francisco, CA 94117; and Mr. Steve Felte Tri-Dam Project, PO Box 1158, Pinecrest, CA 95364.

i. *FERC Contact:* Susan O'Brien, *susan.obrien@ferc.gov*, (202) 502–8449.

j. *Deadline for filing scoping comments*: July 21, 2003.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's rules of practice and procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Scoping comments may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

k. These applications are not ready for environmental analysis at this time.

l. *The existing Spring Gap-Stanislaus Project is composed of four developments*: Relief, Pinecrest, Spring Gap, and Stanislaus. It has a combined capacity of 98 MW.

The existing Donnells-Curtis Transmission Line Project is a 115 kV transmission line. Portions of the transmission line under FERC jurisdiction include an 8-mile segment extending from Donnells Powerhouse to Spring Gap Junction and the 2.2-mile tap line from Beardsley Powerhouse to Beardsley Junction.

The existing Beardsley/Donnell Project is composed of the Beardsley and Donnell Developments and has a combined capacity of 64 MW.

The existing Tulloch Project is composed of a single development and has a capacity of 17.1 MW.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/esubscribenow.htm* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Scoping Process*: The Commission intends to prepare an Environmental Impact Statement (EIS) on the projects in accordance with the National Environmental Policy Act. The EIS will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

Scoping Meetings

FERC staff will conduct one evening meeting and one daytime scoping meeting. The evening scoping meeting is primarily for public input, while the daytime scoping meeting will focus on resource agency and non-governmental organization (NGO) concerns. All interested individuals, organizations, and agencies are invited to attend one or both of the meetings, and to assist the staff in identifying the scope of the environmental issues that should be analyzed in the EIS. The times and locations of these meetings are as follows:

Evening Scoping Meeting

Date: Wednesday, June 18, 2003.
Time: 7:30 p.m.
Place: Stanislaus National Forest Office Building.
Address: 19777 Greenley Road, Sonora, California.

Daytime Scoping Meeting

Date: Thursday, June 19, 2003.
Time: 9 a.m.
Place: Stanislaus National Forest Office Building.
Address: 19777 Greenley Road, Sonora, California.

Copies of the Scoping Document (SD1) outlining the subject areas to be addressed in the EIS are being distributed to the parties on the Commission's mailing list. Copies of the SD1 will be available at the scoping meeting or may be viewed on the web at *http://www.ferc.gov* using the ''FERRIS'' link (*see* item m above).

Site Visit

Due to the logistics involved in traveling to some project locations, there is a need to know the number of attendees in advance. All individuals planning to attend need to call Susan O'Brien, FERC Team Leader, at (202) 502–8449, no later than Thursday, June 12, 2003.

FERC staff and the Applicants and will conduct a 2-day project site visit on June 17 and June 18, 2003, beginning at 7 a.m. each morning. Additionally, on Friday, June 20, 2003, some participants will hike up to Relief Reservoir. All interested individuals, organizations, and agencies are invited to attend any or all three days of the site visit. All participants should meet each morning at the Best Western Sonora Oaks Hotel main entrance, 19551 Hess Ave, Sonora, CA. All participants need to bring their own lunch and are responsible for their own transportation, although we will try to carpool. Four-wheel-drive vehicles are needed to get to some locations.

Tentative schedule for site visit (times given are in Pacific Daylight Savings):

Tuesday June 17

7 am: Site Visit Group departs from Best Western Hotel in Sonora, CA
Morning: Pinecrest Lake, Donnells Reservoir, Donnells Dam
Afternoon: Hells Half Acre, Beardsley day use site, Beardsley Reservoir and Afterbay, Sand Bar diversion and Stanislaus Tunnel intake, Philadelphia Forebay, and Philadelphia Diversion

Wednesday, June 18

7 a.m.: Site Visit Group departs from Best Western Hotel in Sonora, CA
Morning: Stanislaus Power House via Columbia stopping at old Afterbay, continue to Power House. Split into 2 groups. Group 1: Stanislaus Power House, Tulloch via Angels Camp & Highway 4 stopping at Tulloch Resort Group 2: Stanislaus Forebay
Afternoon:-Group 1: Drive through of Conner Estates and Peninsula Estates then on to O'Byrne's Ferry Bridge, Tulloch Dam All: groups rejoin at Goodwin and Tulloch Reservoir, drive through of South Shore Marina and stop for view at Goodwin
5 p.m: Return to Sonora for preparation of evening meeting.

Objectives

At the scoping meetings, the staff will: (1) Summarize the environmental issues tentatively identified for analysis in the EIS; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue; (3) encourage statements from experts and the public on issues that should be analyzed in the EIS, including viewpoints in opposition to, or in support of, the staff's preliminary views; (4) determine the resource issues to be addressed in the EIS; and (5) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis.

Procedures

The meetings are recorded by a stenographer and become part of the formal record of the Commission proceeding on the project.

Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meeting and to assist the staff in defining and clarifying the issues to be addressed in the EIS.

Magalie R. Salas,
Secretary.

[FR Doc. 03–13293 Filed 5–28–03; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

May 21, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Application for new license.

b. *Project No.:* 2174–012.

c. *Date filed*: March 27, 2003.

d. *Applicant:* Southern California Edison.

e. *Name of Project:* Portal Project.

f. *Location:* On Rancheria Creek in Fresno County, near Big Creek, California. The project affects federal lands in the Sierra National Forest, covering a total of 77.67 acres.

g. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791 (a)—825(r).

h. *Applicant Contact:* R. W. Krieger, Vice President, Power Production, Southern California Edison Company, 300 N. Lone Hill Ave., San Dimas, California 91773, (909) 394–8667.

i. *FERC Contact:* Jim Fargo at (202) 219–2848; e-mail *james.fargo@ferc.gov*.

j. *Deadline for filing motions to intervene and protests*: 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, motions to intervene and protests may be filed electronically via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

The Commission's rules of practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application is not ready for environmental analysis at this time.

l. *The existing Portal Project consists of*: (1) A 795-foot-long compacted earth and rock-fill dam; (2) Portal Forebay, with a 325 acre-foot useable storage capacity at elevation 7,185 feet; (3) an open channel spillway at the left abutment of the dam, discharging into Camp 61 Creek; (4) an outlet channel consisting of (a) the Adit 2 tunnel and shaft between Portal Forebay and Ward Tunnel, (b) Ward Tunnel for a distance of about 32,000 feet from Adit 2 to the base of the surge chamber on the tunnel, (c) a rock trap immediately downstream of the surge chamber, and (d) a 1,180-foot-long penstock from the rock trap to where it bifurcates just upstream of the Portal Powerhouse; (5) a 10.8-MW turbine located in the concrete powerhouse; and (6) a 2.5-mile-long 480 kV transmission line.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

n. Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

Magalie R. Salas,

Secretary.

[FR Doc. 03–13294 Filed 5–28–03; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7504–7]

Solicitation of Public Comment Into the Development of a Joint U.S. Environmental Protection Agency (EPA) and American Chemistry Council (ACC) Request for Applications on ''Environmental Statistics Research: Novel Analyses of Human Exposure Related Data;'' Announcement of Memorandum of Understanding Between EPA and ACC on the Procedure for the Joint Solicitation of Research Proposals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: The U.S. Environmental Protection Agency's Office of Research and Development (ORD) and the American Chemistry Council's (ACC) Long-Range Research Initiative (LRI) are interested in issuing joint solicitations for research proposals. A Memorandum of Understanding has been developed that sets forth a public process for bringing together government and industry to engage the best scientists in the research community to assist in improving the quantity and quality of data for use in human health and ecological risk assessment. Discussions have led ORD and ACC to agree to pursue, as a first area of collaboration, a joint request for applications (RFA) in the area of ''Environmental Statistics Research: Novel Analyses of Human Exposure Related Data.'' The purpose of this notice is to solicit specific input into the development of a joint RFA on novel approaches for analysis of human exposure data, and announce a Memorandum of Understanding on the procedures for the public process of issuing joint RFAs.

DATES: Public comment on the draft RFA must be received on or before June 30, 2003.

ADDRESSES: Public comment may be submitted via overnight mail, in person or electronically.

1. By overnight mail, in person, or by courier. You may submit written comments to: Elaine Z. Francis, U.S. Environmental Protection Agency, 1300 Pennsylvania Avenue, NW., Room 51141, Washington, DC 20004

2. Electronically. You may submit written comments electronically by e-mail to: *francis.elaine@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Elaine Z. Francis, U.S. Environmental Protection Agency, 1300 Pennsylvania Avenue, NW., Room 51141, Washington, DC 20004; Telephone: 202–564–6789; Fax: 202–565–2444; E-mail: *francis.elaine@epa.gov.*

SUPPLEMENTARY INFORMATION:

On May 7, 2002, a **Federal Register** notice was published (67 FR 30680) on the availability of a draft document on procedures for the joint solicitation of research proposals by the U.S. Environmental Protection Agency's Office of Research and Development and the American Chemistry Council's Long-Range Initiative, the announcement of a public meeting to discuss the draft document, and solicitation of written public comments. The notice also solicited initial input toward the development of an RFA on novel analyses of human exposure related data, both at the public meeting and through the written comment period. The public meeting was held on May 23, 2002, and the public comment period closed on June 12, 2002.

The public process for the joint solicitation of RFAs was finalized into a Memorandum of Understanding between ORD and ACC. Consistent with the finalized procedures, this notice solicits public comment on the draft RFA. The draft RFA on novel analyses of human exposure related data and the MOU may be obtained electronically through: (1) The EPA Web site: *http://www.epa.gov/ncer/rfa/partners/acc,* (2)

the ACC Web site: *http://www.americanchemistry.com,* (3) the LRI Web site: *http://www.uslri.org,* and (4) the below listed point of contact. Written comments on the draft RFA will be accepted until June 30, 2003.

Dated: May 15, 2003.

Jack Puzak,

Acting Director, National Center for Environmental Research.

[FR Doc. 03–13431 Filed 5–28–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7505–2]

Child-Specific Exposure Factors Handbook

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing the availability of the final document titled, Child-Specific Exposure Factors Handbook (EPA/600/P–00/002B, September 2002). The document was prepared by the Office of Research and Development's National Center for Environmental Assessment (NCEA). The goal of the Child-Specific Exposure Factors Handbook is to consolidate all children's exposure factors data into one document. The document provides a summary of the available and up-to-date statistical data on various factors assessing children's exposures. These factors include drinking water consumption; soil ingestion; inhalation rates; dermal factors including skin area and soil adherence factors; consumption of fruits, vegetables, fish, meats, dairy products, homegrown foods, and breast milk; activity patterns; body weight; consumer products, and life expectancy.

ADDRESSES: The document is available electronically through the NCEA Web site (*www.epa.gov/ncea*). A limited number of paper copies will be available from the EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; telephone: 1–800–490–9198 or 513–489–8190; facsimile: 513–489–8695. Please provide your name, your mailing address, and the title and EPA number of the requested publication.

FOR FURTHER INFORMATION CONTACT: The Technical Information Staff, National Center for Environmental Assessment/Washington Office (8623D), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Telephone: 202–564–3261; fax: 202–565–0050; e-mail: *nceadc.comment@epa.gov.*

Dated: May 15, 2003.

Peter W. Preuss,

Director, National Center for Environmental Assessment.

[FR Doc. 03–13430 Filed 5–28–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7505–4]

Southern Solvents Superfund Site; Notice of Proposed Settlement

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement.

SUMMARY: Under the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), the United States Environmental Protection Agency (''EPA'') proposes to enter into a Prospective Purchaser Agreement (''PPA'') regarding the Southern Solvents Superfund Site in Tampa, Hillsborough County, Florida. EPA is proposing to enter into the PPA with AAA Diversified Services, Inc. Pursuant to the PPA, AAA Diversified Services, Inc., will pay the sum of $80,000 within 30 days of the effective date of the Agreement. EPA will consider public comments on the proposed settlement until June 30, 2003. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is appropriate, improper, or inadequate. Copies of the proposed settlement are available from: Ms. Paula V. Batchelor, U.S. EPA, Region 4, Sam Nunn Atlanta Federal Center, Waste Management Division, 61 Forsyth Street, SW., Atlanta, Georgia 30303. (404) 562–8887.

Written comments may be submitted to Ms. Batchelor within thirty (30) calendar days of the date of this publication.

Dated: May 9, 2003.

Archie Lee,

Chief, CERCLA Program Services Branch, Waste Management Division.

[FR Doc. 03–13429 Filed 5–28–03; 8:45 am]

BILLING CODE 6560–50–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Meeting of the President's Council of Advisors on Science and Technology

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and summary agenda for a meeting of the President's Council of Advisors on Science and Technology (PCAST), and describes the functions of the Council. Notice of this meeting is required under the Federal Advisory Committee Act (FACA).

DATES AND PLACE: June 10, 2003, Washington, DC. The meeting will be held in the Washington Room (roof level) of the Hotel Washington, 15th Street & Pennsylvania Avenue, NW., Washington, DC 20004.

TYPE OF MEETING: Open. For details on the agenda please see the PCAST web site at: *http://www.ostp.gov/PCAST/pcast.html.*

PROPOSED SCHEDULE AND AGENDA: The President's Council of Advisors on Science and Technology is scheduled to meet in open session on Tuesday June 10, 2003, at approximately 9 a.m. The PCAST will: (1) Discuss the status of the work of its workforce-education and information technology manufacturing-competitiveness subcommittees; (2) discuss a draft report from the subcommittee on the science and technology of combating terrorism; and (3) discuss various aspects of its review of the federal National Nanotechnology Initiative. This session will end at approximately 3 p.m. Additional information on the agenda can be found at the PCAST web site at: *http://www.ostp.gov/PCAST/pcast.html.*

PUBLIC COMMENTS: There will be a time allocated for the public to speak on the above agenda items. This public comment time is designed for substantive commentary on PCAST's work topics, not for business marketing purposes. Please submit a request for the opportunity to make a public comment five (5) days in advance of the meeting. Presentations will be reviewed for appropriate content and marketing opportunities will not be provided. The time for public comments will be limited to no more than 5 minutes per person. Written comments are also welcome at any time following the meeting. Please notify Stan Sokul, PCAST Executive Director, at (202) 456–6070, or fax your request/comments to (202) 456–6021.

FOR FURTHER INFORMATION CONTACT: For information regarding time, place and agenda, please call Cynthia Chase at

(202) 456–6010, prior to 3 p.m. on Friday, June 6, 2003. Information will also be available at the PCAST web site at: *http://www.ostp.gov/PCAST/pcast.html.* Please note that public seating for this meeting is limited and is available on a first-come, first-served basis.

SUPPLEMENTARY INFORMATION: The President's Council of Advisors on Science and Technology was established by Executive Order 13226, on September 30, 2001. The purpose of PCAST is to advise the President on matters of science and technology policy, and to assist the President's National Science and Technology Council in securing private sector participation in its activities. The Council members are distinguished individuals appointed by the President from non-Federal sectors. The PCAST is co-chaired by Dr. John H. Marburger, III, the Director of the Office of Science and Technology Policy, and by E. Floyd Kvamme, a Partner at Kleiner Perkins Caufield & Byers.

Stanley S. Sokul,

Executive Director, PCAST, and Counsel, Office of Science and Technology Policy.

[FR Doc. 03–13499 Filed 5–28–03; 8:45 am]

BILLING CODE 3170–01–P

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket 98–67; DA 03–1728]

Notice of Telecommunications Relay Service (TRS) To Remind States and Interstate TRS Providers That the Consumer Complaint Log Summaries Are Due on Tuesday, July 1, 2003

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission notifies the public, state Telecommunications Relay Service (TRS) programs, and interstate TRS providers that the annual consumer complaint log summaries are due on Tuesday, July 1, 2003. Complaint log summaries should include information pertaining to complaints received between June 1, 2002 and May 31, 2003. Complaint log summaries shall include the number of complaints received that allege a violation of federal TRS minimum standards, the date of the complaint, the nature of the complaint, the date of its resolution, and an explanation of the resolution. The Commission requires that this information be included in the complaint log summary for the purpose of alerting the Commission of possible service quality problems.

DATES: State TRS programs and interstate TRS providers must file the annual consumer complaint log summary no later than July 1, 2003.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Erica Myers, (202) 418–2429 (voice), (202) 418–0464 (TTY), or e-mail *emyers@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Public Notice,* CC Docket 98–67, released May 20, 2003. This document notifies state TRS programs and interstate TRS providers that the annual complaint log summary for complaints received between June 1, 2002, and May 31, 2003, is due on Tuesday, July 1, 2003. States and interstate TRS providers who choose to submit by paper must submit an original and four copies of each filing on or before Tuesday, July 1, 2003. To expedite the processing of complaint log summaries, states and interstate TRS providers are encouraged to submit an additional copy to Attn: Erica Myers, Federal Communications Commission, Consumer & Governmental Affairs Bureau, 445 12th Street, SW., Room 6A–432, Washington, DC 20554 or by email at *emyers@fcc.gov.* States and interstate TRS providers should also submit electronic disk copies of their complaint log summaries on a standard 3.5 inch diskette formatted in an IBM compatible format using Word 97 or compatible software. The diskette should be submitted in ''read-only'' mode and must be clearly labeled with the state or interstate TRS provider name, the filing date and captioned ''Complaint Log Summary.''

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Vistronix, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., Room TW–B204, Washington, DC 20554.

The filings and comments will be available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. They may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com.* Filings and comments may also be viewed on the Consumer & Governmental Affairs Bureau, Disability Rights Office homepage at *http://www.fcc.gov/cgb/dro.*

To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–7365 (tty). This *Public Notice* can also be downloaded in Text and ASCII formats at: *http://www.fcc.gov/cgb/dro.*

Federal Communications Commission.

Margaret M. Egler,

Deputy Chief, Consumer & Governmental Affairs Bureau.

[FR Doc. 03–13285 Filed 5–28–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Media Security and Reliability Council

AGENCY: Federal Communications Commission.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons of a meeting of the Media Security and Reliability Council (Council). The meeting will be held at the Federal Communications Commission in Washington, DC.

DATES: Thursday, November 6, 2003, at 10 a.m. to 11:30 a.m.

ADDRESSES: Federal Communications Commission, 445 12th St., SW., Room TW–C305, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Barbara Kreisman at 202–418–1600 or TTY 202–418–7172.

SUPPLEMENTARY INFORMATION: The Council was established by the Federal Communications Commission to bring together leaders of the broadcast and multichannel video programming distribution industries and experts from consumer, public safety and other organizations to explore and recommend measures that would enhance the security and reliability of media facilities and services.

The Council will receive additional reports and best practices recommendations from its working groups. The Council may also discuss such other matters as come before it at the meeting. Members of the general public may attend the meeting. The Federal Communications Commission will attempt to accommodate as many people as possible. Admittance, however, will be limited to the seating available. The public may submit written comments before the meeting to Barbara Kreisman, the Commission's Designated Federal Officer for the Media Security and Reliability Council, by email (bkreisma@fcc.gov) or U.S. mail (2–A666, 445 12th St., SW., Washington, DC 20554). Real Audio and streaming video access to the meeting will be available at *http://www.fcc.gov/*.

Reasonable accommodations for people with disabilities are available upon request. Include a description of the accommodation you will need including as much detail as you can. Also include a way we can contact you if we need more information. Please allow at least 5 days advance notice; last minute request will be accepted, but may be impossible to fill. Send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau: for sign language interpreters, CART and other reasonable accommodations: 202–418–0530 (voice), 202–418–0432 (TTY); for accessible format materials (Braille, large print, electronic files and audio format): 202–418–0531 (voice), 202–418–7365 (TTY).

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–13286 Filed 5–28–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act, Meeting; Open Commission Meeting

The Federal Communications Commission will hold an Open Meeting on the subject listed below on Monday, June 2, 2003, which is scheduled to commence in Room TW–C305, at 445 12th Street, SW., Washington, DC.

Item no.	Bureau	Subject
1	Media	*Title:* 2002 Biennial Regulatory Review—Review of the Commission's Broadcast Ownership Rules and Other Rules Adopted Pursuant to section 202 of the Telecommunications Act of 1996 (MB Docket No. 02–277); Cross-Ownership of Broadcast Stations and Newspapers (MM Docket No. 01–235); Rules and Policies Concerning Multiple Ownership of Radio Broadcast Stations in Local Markets (MM Docket No. 01–317); and Definition of Radio Markets (MM Docket No. 00–244). *Summary:* The Commission will consider a Report and Order concerning its broadcast multiple ownership rules.

With respect to item 1, pursuant to section 1.1200 of the Commission's rules, we find it in the public interest to modify the sunshine period set forth in section 1.1203 of the rules. We modify the sunshine period to permit ex parte presentations to continue through Friday, May 30, 2003.

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 over the Internet from the FCC's Audio/Video Events Web page at *http://www.fcc.gov/realaudio.*

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 *http://www.capitolconnection.gmu.edu.* Audio and video tapes of this meeting can be purchased from CACI Productions, 341 Victory Drive, Herndon, VA 20170, (703) 834–1470, Ext. 19; Fax (703) 834–0111.

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, Qualex International (202) 863–2893; Fax (202) 863–2898; TTY (202) 863–2897. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio tape. Qualex International may be reached by e-mail at *Qualexint@aol.com.*

Notice: Due to the elevated homeland security alert announced May 20, 2003, the FCC has taken additional security precautions that will limit visitor access to the FCC headquarters building in Washington, DC. Until further notice, the Maine Avenue lobby is closed. All visitors must enter the building through the 12th Street lobby, and will require an escort at all times in the building.

Federal Communications Commission.

Dated: May 23, 2003.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–13512 Filed 5–27–03; 10:03 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

AGENCY: Federal Election Commission.

Date & time: Tuesday, June 3, 2003, at 10 a.m.

Place: 999 E Street, NW., Washington, DC.

Status: This meeting will be closed to the public.

Items to be discussed:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

Date & time: Wednesday, June 4, 2003, at 10 a.m.

Place: 999 E Street, NW., Washington, DC (Ninth Floor).

Status: This oral hearing will be open to the public.

Matter before the Commission: Keyes 2000, Inc., Committee (LRA #570).

Date & time: Thursday, June 5, 2003 at 10 a.m.

Place: 999 E Street, NW., Washington, DC (Ninth Floor).

Status: This meeting will be open to the public.

Items to be discussed:

Correction and Approval of Minutes.
Administrative Matters.

Date & time: Friday, June 6, 2003 at 10 a.m.

Place: 999 E Street, NW., Washington, DC (Ninth Floor).

Status: This hearing will be open to the public.

Matters before the Commission:
Public financing of Presidential candidates and nominating conventions.

FOR FURTHER INFORMATION CONTACT: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 03–13587 Filed 5–27–03; 2:32 pm]

BILLING CODE 6715–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011756–001.

Title: New World Alliance/Evergreen Slot Exchange Agreement.

Parties: American President Lines, Ltd./APL Co. Pte Ltd. (acting as one party) (''APL'')
Hyundai Merchant Marine Co. Ltd. (''Hyundai'')
Mitsui O.S.K. Lines, Ltd. (''MOL'')
Evergreen Marine Corp. (Taiwan) Ltd. (''Evergreen'')

Synopsis: The proposed agreement modification deletes Thailand and Malaysia from the geographic scope, revises the number of vessels deployed by the parties in the trade, revises the average capacity of the parties' vessels, revises the list of services on which the parties exchange slots, and adds specific slot allocations for each party. It also republishes the agreement in a second edition and establishes an initial 12-month period for the second edition of the agreement.

Dated: May 22, 2003.

By Order of the Federal Maritime Commission.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–13324 Filed 5–28–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 03–04]

Diversified Freight Logistics, Inc. v. National Shipping Co. of Saudi Arabia; Notice of Filing of Complaint and Assignment

Notice is given that a complaint was filed by Diversified Freight Logistics, Inc. (''Complainant''), against the National Shipping Company of Saudi Arabia (''Respondent''). The complaint was served on May 20, 2003. Complainant alleges that Respondent violated sections 10(b)(3), 10(b)(4)(E), 10(b)(8) and 10(d)(1) of the Shipping Act, 46 U.S.C. app. 1709(b)(3), 1709(b)(4)(E), 1709(b)(8) and 1709(d)(1) by retaliating against it by initiating a civil suit against Complainant for ''lost freight'' arising from a canceled booking; by failing to compromise or settle its claim for lost freight; by imposing unreasonable prejudice or disadvantage by failing to seek reimbursement or commence suit against other forwarders or principles which have canceled bookings; and by failing to establish reasonable practices that allow a party to cancel bookings without peril of suit. Complainant seeks an order finding Respondent to have violated the sections cited above, a cease and desist order and reparations for certain expenses and fees.

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by May 19, 2004, and the final decision of the Commission shall be issued by September 16, 2004.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–13323 Filed 5–28–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuance

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984, as amended by the Ocean Shipping Reform Act of 1998 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License No.	Name/Address	Date reissued
2724NF	Air 7 Seas Transport Logistics, Inc., 1815 Houret Court, Milpitas, CA 95035–6823	April 23, 2003.
10355N	Finlay's Import-Export, Inc. dba Finlay's Ship To Jamaica, 8700 NW 7th Avenue, Miami, FL 33150.	April 3, 2003.
2189F	Stavers Corporation, 165 Truman Terrace, Paramus, NJ 07652	April 13, 2003.
1294NF	U.S. Express, Inc., 137–44 94th Avenue., Jamaica, NY 11435	September 1, 2002.

Sandra L. Kusumoto,

Director, Bureau of Consumer Complaints and Licensing.

[FR Doc. 03–13322 Filed 5–28–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding date shown below:

License Number: 16628N.
Name: Air & Sea Pak Co. dba Corrigan Air & Sea Cargo Systems.
Address: 6170 Middlebelt Road, Romulus, MI 48174.
Date Revoked: April 28, 2003.
Reason: Failed to maintain a valid bond.

License Number: 11242N.
Name: Aloyd International Corp.
Address: 149–09 183rd Street, Springfield Gardens, NY 11413.
Date Revoked: March 31, 2003.
Reason: Failed to maintain a valid bond.

License Number: 4085F.
Name: American Logistics & Purchasing Services, Ltd.
Address: 1610 Parkview Avenue, Seaford, NY 11783.
Date Revoked: April 19, 2003.
Reason: Failed to maintain a valid bond.

License Number: 3356F.
Name: Arrow Cargo, Inc.
Address: 3231 S. Gulley Road, Suite D, Dearborn, MI 48124.
Date Revoked: May 7, 2003.
Reason: Failed to maintain a valid bond.

License Number: 1530F.
Name: Colombo Services, Inc.
Address: 4000–A Airline Drive, Suite A, Houston, TX 77022.
Date Revoked: May 7, 2003.
Reason: Failed to maintain a valid bond.

License Number: 16499N.
Name: DSM Freight, Inc.
Address: 280 SW 99th Terrace, Pembroke Pines, FL 33025.
Date Revoked: May 1, 2003.
Reason: Failed to maintain a valid bond.

License Number: 17304F.
Name: Direct Worldwide Logistics, Inc.
Address: 7520 Lawndale Avenue, Houston, TX 77012.
Date Revoked: March 28, 2003.
Reason: Failed to maintain a valid bond.

License Number: 17572N.
Name: Impex of Doral Logistics, Inc.
Address: 7275 NW 87th Avenue, Miami, FL 33166.
Date Revoked: October 16, 2002.
Reason: Failed to maintain a valid bond.

License Number: 17077F.
Name: J. Powers International, Inc.
Address: 2501 South State, Suite 100–B, Little Rock, AR 72206.
Date Revoked: May 14, 2003.
Reason: Failed to maintain a valid bond.

License Number: 16356N.
Name: Jagremar Marine, Inc.
Address: 15490 Vickery Drive, Houston, TX 77032.
Date Revoked: May 1, 2003.
Reason: Failed to maintain a valid bond.

License Number: 13754N.
Name: L.A.S. Incorporated.
Address: 8 Hook Road, Bayonne, NJ 07002.
Date Revoked: May 11, 2003.
Reason: Failed to maintain a valid bond.

License Number: 16353N.
Name: Mittercon International, Inc.
Address: 119 Village Street, Suite A, Slidell, LA 70458.
Date Revoked: May 7, 2003.
Reason: Failed to maintain a valid bond.

License Number: 16529N.
Name: Newmark Shipping Ltd. dba R S Freight Inc. dba R S F Inc.
Address: 4455 Torrance Blvd. Suite 848, Torrance, CA 90503.
Date Revoked: May 1, 2003.
Reason: Failed to maintain a valid bond.

License Number: 4133F.
Name: Overseas Trading & Shipping Co., Inc.
Address: 2654 Pittman Drive, Silver Spring, MD 20910.
Date Revoked: May 1, 2003.
Reason: Failed to maintain a valid bond.

License Number: 4273NF.
Name: Primar International, Inc.
Address: 15402 Vantage Parkway East, Suite 314, Houston, TX 77032.
Date Revoked: May 7, 2003.
Reason: Failed to maintain valid bonds.

License Number: 16731N.
Name: Providence Services, Inc.
Address: 8565 NW 68th Street, Miami, FL 33166.
Date Revoked: April 25, 2003.
Reason: Failed to maintain a valid bond.

License Number: 16829NF.
Name: Rail Van LLC dba Multimodal Transportation Division of Rail Van, Inc. dba Global Logistics Services.
Address: 400 West Wilson Bridge Road, Worthington, OH 43082.
Date Revoked: May 4, 2003.
Reason: Failed to maintain valid bonds.

License Number: 11170N.
Name: Sage Freight Systems Inc. dba Sage Container Lines.
Address: 182–30 150th Road, Suite 108, Jamaica, NY 11413.
Date Revoked: April 26, 2003.
Reason: Failed to maintain a valid bond.

License Number: 18322F.
Name: Shiprotectors International, Inc.
Address: 211 East Ocean Blvd., Suite 245, Long Beach, CA 90802.
Date Revoked: May 14, 2003.
Reason: Surrendered license voluntarily.

License Number: 17583N.
Name: Sino-America Express, Inc.
Address: P.O. Box 1495, 13523 Tobinn Manor Drive, Cypress, TX 77429.
Date Revoked: April 1, 2003.
Reason: Surrendered license voluntarily.

License Number: 17169F.
Name: South West Marine Inc.
Address: 400 C Ansin Blvd., Hallandale, FL 33009.
Date Revoked: March 1, 2002.
Reason: Failed to maintain a valid bond.

License Number: 6098N.
Name: Sunshine Express Line, Inc.
Address: 3250 NW, North River Drive, Miami, FL 33142.
Date Revoked: May 11, 2003.
Reason: Failed to maintain a valid bond.

License Number: 3536NF.
Name: Supertrans International Inc.
Address: 8635 Aviation Blvd., Inglewood, CA 90301.
Date Revoked: March 21, 2003.
Reason: Failed to maintain valid bonds.

License Number: 3478F.
Name: Sextant Overseas Shipping Corp.
Address: P.O. Box 126, Enid Road, Summit, NY 12175.
Date Revoked: April 13, 2003.
Reason: Failed to maintain a valid bond.

License Number: 3443N.

Name: Tradewinds Shipping Corp.
Address: 420 Sackett Point Road, Suite Unit 4B, North Haven, CT 06473–3171.
Date Revoked: April 20, 2003.
Reason: Failed to maintain a valid bond.

License Number: 12740N.
Name: USA International Business Connections Corp.
Address: 14313 Bonelli Street, City of Industry, CA 91746.
Date Revoked: April 27, 2003.
Reason: Failed to maintain a valid bond.

License Number: 17413NF.
Name: Venture Transport, Inc.
Address: 314 N. Post Oak Lane, Houston, TX 77024.
Date Revoked: April 18, 2003.
Reason: Failed to maintain valid bonds.

License Number: 7877N.
Name: X-Press Freight Forwarders, Inc.
Address: Calle A Km 1.5 Lot 12, URB Industrial Ville Park, Savana Abajo, Carolina, Puerto Rico 00984.
Date Revoked: May 14, 2003.
Reason: Failed to maintain a valid bond.

Sandra L. Kusumoto,
Director, Bureau of Consumer Complaints and Licensing.

[FR Doc. 03–13321 Filed 5–28–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as a Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR part 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel Operating Common Carrier Ocean Transportation Intermediary Applicants

Hye Mi Express U.S.A., Inc., 3545 McCall Place, Suite A, Doraville, GA 30340, Officers: Yong J. Kim, Managing Director (Qualifying Individual), Seung Ku Cho, President.

Nanix Express Int'l Inc., 175–41 148th Road, Jamaica, NY 11434, Officers: Edmond Yau, Vice President (Qualifying Individual), Lenny Poon, President.

Rapid Cargo & Logistics, Inc., 11222 La Cienega Blvd., #600, Inglewood, CA 90304, Officers: Brendan Sheen, Managing Director (Qualifying Individual), Yong ki Hong, President.

Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants

Global Container Line, Inc., 1930 Sixth Avenue South, Seattle, WA 98134, Officers: W. Guy Fox, Exec. Vice President (Qualifying Individual), Jason M. Totah, President.

Dated: May 22, 2003.

Bryant L. VanBrakle,
Secretary.

[FR Doc. 03–13320 Filed 5–28–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Board of Governors of the Federal Reserve System (Board)

ACTION: Notice and request for comment

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Board, the Federal Deposit Insurance Corporation (FDIC), and the Office of the Comptroller of the Currency (OCC) (collectively, the ''agencies''), may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), propose to extend without revision the following currently approved information collection: the Country Exposure Report for U.S. Branches and Agencies of Foreign Banks (FFIEC 019). The Board is publishing this request for extension on behalf of the agencies. At the end of the comment period, the comments and recommendations received will be analyzed to determine whether the FFIEC and the agencies should modify the information collection. The Board will then submit the reports to OMB for review and approval.

DATES: Comments must be submitted on or before July 28, 2003.

ADDRESSES: Interested parties are invited to submit written comments to the agency listed below. All comments will be shared among the agencies.

Written comments, which should refer to ''Country Exposure Report for U.S. Branches and Agencies of Foreign Banks, 7100–0213,'' may be mailed to Ms. Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, N.W., Washington, DC 20551. However, because paper mail in the Washington area and at the Board of Governors is subject to delay, please consider submitting your comments by e–mail to regs.comments@federalreserve.gov, or faxing them to the Office of the Secretary at 202–452–3819 or 202–452–3102. Members of the public may inspect comments in Room MP–500 between 9:00 a.m. and 5:00 p.m. on weekdays pursuant to 261.12, except as provided in 261.14, of the Board's Rules Regarding Availability of Information, 12 CFR 261.12 and 261.14.

A copy of the comments may also be submitted to the OMB desk officer for the agencies: Joseph F. Lackey, Jr., Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503 or electronic mail to jlackeyj@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Additional information or a copy of the collection may be requested from Cindy Ayouch, Federal Reserve Board Clearance Officer, (202) 452–3829, Division of Research and Statistics, Board of Governors of the Federal Reserve System, 20th and C Streets, N.W., Washington, D.C. 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869, Board of Governors of the Federal Reserve System, 20th and C Streets, N.W., Washington, D.C. 20551.

SUPPLEMENTARY INFORMATION:

Proposal to Extend For Three Years Without Revision the Following Currently Approved Information Collection:

Report title: Country Exposure Report for U.S. Branches and Agencies of Foreign Banks
Form number: FFIEC 019.
OMB number: 7100–0213.
Frequency of response: Quarterly.
Affected Public: U.S. branches and agencies of foreign banks.
Number of respondents: 185.
Estimated average hours per response: 10 hours.
Estimated Annual reporting hours: 7,400 hours.

General Description of Report: This information collection is mandatory: 12 U.S.C. 3906 for all agencies; 12 U.S.C. 3105 and 3108 for the Board of Governors of the Federal Reserve System; sections 7 and 10 of the Federal Deposit Insurance Act (12 U.S.C. 1817, 1820) for the Federal Deposit Insurance Corporation; and the National Bank Act (12 U.S.C. 161) for the Office of the Comptroller of the Currency). This information collection is given confidential treatment. (5 U.S.C. 552(b)(8)). Small businesses (that is, small U.S. branches and agencies of foreign banks) are affected.

Abstract: All individual U.S. branches and agencies of foreign banks that have more than $30 million in direct claims on residents of foreign countries must file the FFIEC 019 report quarterly. Currently, all respondents report adjusted exposure amounts to the five largest countries having at least $20 million in total adjusted exposure. The Agencies collect this data to monitor the extent to which such branches and agencies are pursuing prudent country risk diversification policies and limiting potential liquidity pressures. No changes are proposed to the FFIEC 019 reporting form or instructions.

Request for Comment

Comments are invited on:

a. Whether the information collections are necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

b. The accuracy of the agencies' estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this notice will be shared among the agencies and will be summarized or included in the Board's request for OMB approval. All comments will become a matter of public record. Written comments should address the accuracy of the burden estimates and ways to minimize burden including the use of automated collection techniques or the use of other forms of information technology as well as other relevant aspects of the information collection request.

Board of Governors of the Federal Reserve System, May 22, 2003.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 03–13344 Filed 5–28–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 11, 2003.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. Farbod S. Zohouri, Flowery Branch, Georgia; to acquire voting shares of Texico Bancshares Corporation, Texico, Illinois, and thereby indirectly acquire voting shares of Texico State Bank, Texico, Illinois.

Board of Governors of the Federal Reserve System, May 22, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–13346 Filed 5–28–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 20, 2003.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Blackhawk Bancorp, Inc., Beloit, Wisconsin; to acquire 100 percent of the voting shares of DunC Corp., Rockford, Illinois, and thereby indirectly acquire voting shares of First Bank, BC, Capron, Illinois.

Board of Governors of the Federal Reserve System, May 22, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–13345 Filed 5–28–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

TIME AND DATE: 11 a.m., Monday, June 2, 2003.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Assistant to the Board; 202–452–2955.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: May 23, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–13504 Filed 5–27–03; 8:47 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the President's Council on Bioethics on June 12–13, 2003

AGENCY: The President's Council on Bioethics, HHS.

ACTION: Notice.

SUMMARY: The President's Council on Bioethics will hold its eleventh meeting, at which it will discuss, among other things, current research into overcoming immune rejection in embryonic and adult stem-cell therapies (Silviu Itescu, M.D., Columbia University College of Physicians and Surgeons). The Council will hear testimony from various interested parties on current and possible future regulation of biotechnologies that touch the beginnings of human life. Panel 1: Robert Brzyski, M.D., Society for Assisted Reproductive Technology; John Bruchalski, M.D., Tepeyac Family Center, Wash., DC (invited); Kathy Hudson, Ph.D., Genetics and Public Policy Center; Pamela Madsen, American Infertility Association; Mary Mahowald, Ph.D. (University of Chicago); and David Smith, Ph.D., Indiana University. Panel 2: Richard Doerflinger, U.S. Catholic Bishops Conference; Andrew Kimbrell, International Center for Technology Assessment; William Kristol, Bioethics Project; Michael Manganiello, Coalition for the Advancement of Medical Research; Maxine Singer, Ph.D., Chair, Committees on Science, Engineering, & Public Policy, National Academies; Michael Werner, Biotechnology Industry Organization. Subjects discussed at past Council meetings (and potentially touched on at this meeting) include: human cloning; embryonic stem cell research; the patentability of human genes, tissues, and organisms; assisted reproduction; preimplantation genetic diagnosis (PGD) and screening; sex selection techniques; inheritable genetic modification (IGM); international models of biotech regulation; organ procurement for transplantation; extra-therapeutic powers to enhance or improve human mood, memory, and muscles; and research to extend the human lifespan.

DATES: The meeting will take place Thursday, June 12, 2003, from 9:00 am to 5:15 pm ET; and Friday, June 13, 2003, from 8:30 am to 12:30 pm ET.

ADDRESSES: Wyndham Washington DC, 1400 M Street, NW., Washington, DC 20005.

Public Comments: The meeting agenda will be posted at *http://www.bioethics.gov.* Members of the public may comment, either in person or in writing. A period of time will be set aside during the meeting to receive comments from the public, beginning at 11:30 am, on Friday, June 13. Comments will be limited to no more than five minutes per speaker or organization. Please inform Ms. Diane Gianelli, Director of Communications, in advance of your intention to make a public statement, giving her your name, affiliation, and a brief description of the topic or nature of your comments. To submit a written statement, mail or e-mail it to Ms. Gianelli at one of the addresses given below.

FOR FURTHER INFORMATION CONTACT: Ms. Diane Gianelli, Director of Communications, The President's Council on Bioethics, Suite 600, 1801 Pennsylvania Avenue, Washington, DC 20006. Telephone: 202/296–4669. E-mail: *info@bioethics.gov.* Web site: *http://www.bioethics.gov.*

Dated: May 21, 2003.

Dean Clancy,

Executive Director, The President's Council on Bioethics.

[FR Doc. 03–13325 Filed 5–28–03; 8:45 am]

BILLING CODE 4110–60–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the inaugural meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS). The meeting will also be webcast. (*See also* **Federal Register**: May 7, 2003, Volume 68, Number 88, Page 24488.)

The meeting will be held from 9 a.m. to 6 p.m. on June 11, 2003 and 8:30 a.m. to 5 p.m. on June 12, 2003 at the Wyndham Hotel, 1400 M Street, NW., Washington, DC. The meeting will be open to the public with attendance limited to space available.

The first day will be devoted to presentations on and discussion of the status and future directions of genetic technologies, their potential applications, and the issues surrounding their use. The second day will involve deliberations aimed at formulating the SACGHS issues agenda. Time will be provided each day for public comment.

Under authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues.

The draft meeting agenda and other information about SACGHS, including information about access to the webcast, will be available at the following Web site: *http://www4.od.nih.gov/oba/sacghs.htm.* Individuals who wish to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or E-mail at *sc112c@nih.gov.* The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13366 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry (ATSDR)

Solicitation of Interested Persons To Serve as Special Consultants to the Community Tribal Subcommittee (CTS) of the ATSDR Board of Scientific Counselors

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces ATSDR's intent to fill 3 Special Consultant vacancies on the Community and Tribal Subcommittee of ATSDR's Board of Scientific Counselors.

Background:

The Community and Tribal Subcommittee is composed of four members of ATSDR's Board of Scientific Counselors (BSC). Activities of the CTS provide the BSC with a formal vehicle for citizens input. In 1994, three community and tribal representatives were selected to serve as Special Consultants to CTS. At the end of their tenure, it was decided to increase the number of Special Consultants from three to eleven in order to bring a wider spectrum of representation from community and tribal members who live near hazardous waste sites, or are otherwise affected by hazardous substances in the community environment.

To express interest in serving as a Special Consultant to CTS and obtain additional information, contact: James Tullos, Designated Federal Official, CTS, ATSDR M/S E–42, 1600 Clifton Road, NE., Atlanta, GA 30033, Telephone 1–888–422–8737.

SUPPLEMENTARY INFORMATION: ATSDR conducts public health-related activities at hazardous waste sites and releases, pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*). ATSDR established the Board of Scientific Counselors, which is chartered under the Federal Advisory Committee Act (5 U.S.C. app.). In order to obtain input from communities and tribes located near superfund sites or hazardous waste sites, the CTS is recruiting three community and tribal representatives as consultants to the CTS.

The Community and Tribal Subcommittee's objective is to provide the BSC and ATSDR with the views and recommendations of community and tribal representatives on ATSDR's community involvement programs, practices, policies, and other relevant issues impacting communities and tribes who live near Superfund and hazardous waste sites. The subcommittee reviews ATSDR's community involvement programs and policies; provides advice, findings, and recommendations to the Board on these issues; and brings broad-based community and tribal involvement issues to the attention of the Board. The Community and Tribal Subcommittee will present its findings, advice, and recommendations to the full Board. The BSC will discuss and review reports of the subcommittee and may forward recommendations to the Agency for action. The Community and Tribal Subcommittee will periodically meet and/or hold conference calls. A group consisting of Special Consultants, the CTS Chair, and the Designated Federal Official will review the applications and develop a short list to be recommended to the Agency for consideration. The Agency, in consultation with the BSC Chair, will then select the three community representatives to fill the vacancies. Accordingly, any person who lives in a community affected by a National Priority List site or other hazardous waste site; who is a representative of a group that works at local, regional, or national locations within these communities; or who wishes to be considered for serving as a special consultant on this subcommittee, should write or call the ATSDR contact person listed above to obtain additional information.

Application: Please complete the following application and return it to the address listed by Monday, June 30, 2003.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and ATSDR.

Diane C. Allen,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

BILLING CODE 4163–70–P

NOMINATION APPLICATION

Special Consultant

for the Community/Tribal Subcommittee

ATSDR
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

Reply By: June 30, 2003

Submit Applications To:	(Reply By: Mail, Fax, or E-Mail)	
James Tullos Designated Federal Official, CTS ATSDR (MS E-42) 1600 Clifton Road, NE Atlanta, Georgia 30033	Phone: Fax: E-Mail:	1-888-422-8737 1-404-498-0074 JTullos@cdc.gov

Applicant Information			E-Mail Address:	
Last Name	**Initial**	**First Name**	**Phone:**	
			Fax:	
Street Address		**City**	**State**	**Zip**
Employment and Employer(s) for last five years:				

Please check the corresponding box for your response to the following questions: please keep any written responses brief.

1. Do you live in a community or on a reservation that contains a site contaminated with toxic substances or are you a member of an organization that works on environmental health/toxic substances issues with such affected communities/tribes? (Check all that apply)

☐ Yes, live in such a community/reservation ☐ No, none of the above

☐ Yes, member of such an organization **(If no, go to question # 9)**

2. What type of site is it?

- ☐ National Priorities List (Superfund NPL)
- ☐ Department of Energy
- ☐ Department of Defense
- ☐ State level
- ☐ Not sure/don't know
- ☐ Other

3. What is the status of site cleanup?

- ☐ Cleanup underway
- ☐ No work done
- ☐ Cleanup completed
- ☐ Not sure/don't know

4. How would you characterize your community/tribe?

- ☐ Rural
- ☐ Suburban
- ☐ Urban
- ☐ Tribal Lands
- ☐ Not sure/don't know

5. How would you characterize the racial/ethnic makeup of your community/tribe?

- ☐ White
- ☐ African-American
- ☐ Hispanic
- ☐ Asian
- ☐ Native American
- ☐ Mixed/no group predominate
- ☐ Not sure/don't know

6. How would you characterize the economic status of your community/tribe?

- ☐ Lower income
- ☐ Middle income
- ☐ Upper income
- ☐ Not sure/don't know

7. Do you believe your personal/family health has been harmed due to exposure to toxic substances in the environment?

- ☐ Yes
- ☐ Possibly
- ☐ No

7a. If you are a tribal member, is contamination of traditional food supply thought to be a problem?

- ☐ Yes
- ☐ Possibly
- ☐ No

8. Are you a member of a community/tribal organization focused on the site?

☐ Yes ☐ No

8a. If yes, please describe:

_____

_____

_____

_____

_____

_____

9. Are you familiar with the Agency for Toxic Substances and Disease Registry (ATSDR)?

☐ Yes ☐ No

10. Have you either sought assistance from, or previously been involved with ATSDR?

☐ Yes ☐ No

11. Has ATSDR sponsored a health assessment or health study in your community?

☐ Yes ☐ No ☐ Not sure/don't know

12. Have you attended other national or regional ATSDR meetings in the past five (5) years?

☐ Yes ☐ No

13. Are you a member of an organization – other than the one you may have noted in question eight (8) – focused on toxic substances/environmental health?

☐ Yes ☐ No

13a. If yes, what is the scope of the organization?

☐ Local ☐ Regional ☐ National

13b. Please describe the organization:

_____

_____

_____

_____

14. How many years have you been involved in toxic substance/environmental health issues?

☐ 1, ☐ 2, ☐ 3, ☐ 4, ☐ 5, ☐ 7, ☐ 9, ☐ More than 10

15. How many hours on average can you make available for telephone calls, periodic meetings, and review of materials?

____ Hours per week _____ Hours per month

16. Have you in the past or are you participating in an advisory group similar in structure to the Community/Tribal Subcommittee?

☐ Yes ☐ No

16a. If yes, please describe the group and your role:

_____

_____

_____

_____

_____

_____

17. **QUALIFICATION/BACKGROUND:** Please briefly note your knowledge of/experience with toxic substances/environmental health issues. List relevant self-education/research, workshops attended, and other formal training.

_____

_____

_____

_____

_____

_____

_____

_____

_____

18. **CURRENT ISSUES:** What would you do to develop national or regional guidelines or policies to enhance community involvement surrounding ATSDR activities?

_____

_____

_____

_____

_____

_____

19. **EXPECTATIONS:** What type of input, recommendations, and advice do you envision the Community/Tribal Subcommittee providing, and what type of outreach would you do in order to formulate your recommendations, via the CTS, to the Board of Scientific Counselors?

_____

_____

_____

_____

_____

_____

_____

_____

20. What is your ethnic origin/race?

[FR Doc. 03–13377 Filed 5–28–03; 8:45 am]
BILLING CODE 4163–70–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Program Announcement Number 03087]

Polychlorinated Biphenyls Exposure and Adverse Health Effects in Anniston, Alabama; Notice of Availability of Funds

Application Deadline: June 30, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized in Sections 104(i)(1)(E), (7) and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9604 (i)(1)(E), (7) and (15)). The Catalog of Federal Domestic Assistance number is 93.206.

B. Purpose

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program to conduct research on the impact of polychlorinated biphenyls (PCBs) exposure on human health in Anniston, Alabama. This program addresses the ''Healthy People 2010'' focus area of Environmental Health.

The purpose of this program is to: (1) Collect baseline information and serum PCBs from a sample of Anniston residents; (2) study the relationship between exposure to PCBs and adverse health effects, such as cancer, neurobehavioral disorders, birth defects, and immune function; and (3) inform and educate residents about PCB exposure in their community.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the ATSDR: (1) develop and provide reliable and understandable information for people in affected communities and tribes, and for stakeholders, and (2) ascertain the relationship between exposure to toxic substances and disease.

C. Eligible Applicants

Applications may be submitted by:

- Health departments of States or their *bona fide* agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.
- Federally recognized Indian tribal governments.
- State-based institutions (this includes universities, colleges, and research institutions.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

Special Requirements

Minimal Applicant Requirements

1. A documented link between the Anniston community and the applicant.
2. Experience with community outreach and health education to provide support and information.
3. The investigators should be prepared to work collaboratively with ATSDR and community leaders to achieve the goals of this solicitation.
4. The investigators should be prepared to meet on a periodic basis with community representatives.

D. Funding

Availability of Funds

Approximately $1,500,000 is available in FY 2003 to fund up to two awards. It is expected that the average award will be $750,000, ranging from $600,000 to $1,500,000. It is expected that the awards will begin on or about August 1, 2003, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Funds may be expended for reasonable program purposes, such as, personnel, travel, supplies and services. Funds for contractual services may be requested; however, the primary recipient of ATSDR funds must perform a substantive role in carrying out project activities and not merely serve as a conduit for an award to another party or provide funds to an ineligible party. Equipment may be purchased with these funds; however, the equipment proposed should be appropriate and reasonable for the research activity to be conducted. Equipment may be acquired only when authorized and the application should provide a justification of the need to acquire equipment, the description, and the cost of purchase versus lease. To the greatest extent practicable, equipment and products purchased with ATSDR funds should be American made. ATSDR retains the right to request the return, at the completion of the project period, of all equipment in operable condition purchased with grant funds.

Recipient Financial Participation

Matching funds are not required for this program.

Funding Preferences

Preference will be given to the following: applicants who are located in the southeastern region of the United States, applicants who have support from the Anniston community as evidenced by letters of support, applicants who demonstrate collaborative effort with other institutions, or projects which avoid a duplication of study objectives.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed in 1. Recipient Activities, and ATSDR will be responsible for the activities listed in 2. ATSDR Activities.

1. Recipient Activities

a. Develop a study proposal that examines the relationship between exposure to PCBs and an adverse health effect, such as cancer, neurobehavioral disorders, birth defects, and/or immune function. Protocol (study design and end point(s) under investigation) and data collection instruments will be developed by applicant, in consultation with ATSDR, and approved prior to project implementation. A recommended time line is available in Attachment IV. All attachments referenced in this announcement are posted with the announcement on the CDC Web site.

b. Meet in Anniston, Alabama, at least twice in the first year with ATSDR and Environmental Protection Agency Region IV staff to review available exposure data to help define the exposed population(s).

c. At the conclusion of the study, share all data collected through these activities with ATSDR. These data may be used by ATSDR to further characterize potential exposure pathways.

d. Through letters of support, provide evidence of on-going collaborative efforts with community representatives, local elected officials, state and local health departments, etc., to enhance communication and information exchange with the Anniston community (Attachment V).

e. Establish a mechanism to work with community leaders in Anniston, Alabama, on a periodic basis throughout the study period to gather input on study design issues, and receive feedback regarding outreach, participation, and education.

f. Meet annually with ATSDR and other awardee(s) in Atlanta, Georgia, to coordinate planned efforts and review progress.

g. Disseminate research results to community members, and publish in written format for distribution.

2. ATSDR Activities

a. Provide epidemiologic guidance and administrative support to achieve program goals.

b. In collaboration with the recipient, develop a research protocol for Institutional Review Board (IRB) review by all cooperating institutions

participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Develop and provide to recipient a number of baseline questions for data collection related to the participant's exposure history.

d. In collaboration with the Environmental Protection Agency Region IV and the recipient(s), coordinate meetings in Anniston, Alabama, at least twice in the first year to review available exposure data to better define exposed population(s).

e. Participate in periodic meetings with community leaders in Anniston, Alabama, to gather input on study design issues, and receive feedback regarding outreach, participation, and education throughout the study period.

f. Facilitate external peer review of the study protocol and the final report.

g. Provide assistance with the dissemination of information resulting from this project, including the review and publication of a final report.

h. Facilitate an annual meeting between awardee(s) in Atlanta, Georgia, to coordinate planned efforts and review progress.

F. Content

Applications

The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan.

The narrative should be no more than 45 pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font. The narrative should consist of, at a minimum, a Proposed Research Plan, Objectives, Methods, Evaluation, Budget, and Time line. The program plan should address activities to be conducted over the entire three-year project period.

G. Submission and Deadline

Application Forms

Submit the signed original and two copies of PHS 5161–1 (OMB 0920–0428). Forms are available at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.* If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) at: 770–488–2700. Application forms can be mailed to you.

Submission Date, Time, and Address

The application must be received by 4 p.m. eastern time June 30, 2003. Submit the application to: Technical Information Management—PA #03087, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd, Atlanta, GA 30341–4146.

Applications may not be submitted electronically.

CDC Acknowledgment of Application Receipt

A postcard will be mailed by PGO-TIM, notifying you that CDC has received your application.

Deadline

Applications shall be considered as meeting the deadline if they are received before 4 p.m. eastern time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Application

An independent review group appointed by ATSDR will evaluate each application against the following criteria:

1. Goals and Objectives (20 percent)

The extent to which the applicant clearly identifies specific, measurable, and scientifically sound goals and objectives.

2. Study Design and Methods (20 percent)

a. Adequacy of the study design and methodology for accomplishing the stated goals and objectives.

b. The degree to which efficient and innovative approaches are proposed in collaboration with other institutions.

c. The extent to which the applicant's plans and schedule proposed for accomplishing the activities to be carried out in this project are clearly stated, are realistic given the length of the funding period, and can be achieved within the proposed budget.

d. Applicant provides opportunities to collaborate with Anniston community leaders to develop final study protocol.

3. Community Involvement, Education, and Dissemination of Results (20 percent)

a. Adequacy of plan to address community concerns by establishing partnerships with community representatives, local environmental and health agencies, and other relevant public and private groups and organizations prior to project implementation.

b. Adequacy of plans to create formal lines of communication with Anniston leaders on a periodic basis, including representation from various disciplines and backgrounds.

c. The degree to which efficient and innovative approaches are proposed to educate the community about PCB exposure.

d. Adequacy of methods to work with the community to disseminate study results.

4. Understanding of the Problem (10 percent)

a. The applicant's understanding of the problems facing the residents of Anniston, Alabama.

b. The applicant should demonstrate an understanding of scientific and epidemiologic issues when conducting environmental research.

c. Relevance of the proposed program to these and related problems.

5. Program Personnel (10 percent)

a. Applicant's technical experience and understanding in the areas of PCBs, environmental epidemiology, health education/community outreach, etc.

b. Qualifications and time allocation of the professional staff to be assigned to this project.

c. Extent to which the management staff and their working partners are clearly described.

6. Facilities and Resources (10 percent)

The adequacy of the applicant's facilities, equipment, and other resources available for performance of this project.

7. Measures of Effectiveness (10 percent)

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the

cooperative agreement. Measures of effectiveness must relate to the performance goals as stated in the Purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application.

8. *Human Subjects:* does the application adequately address the requirements of 45 CFR part 46 for the protection of human subjects? (Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.)

9. Budget Justification (Not Scored)

The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of funds.

10. Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? (Not scored.) This includes:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

I. Other Requirements

Technical Reporting Requirements

1. Provide CDC with an original plus two copies of an interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, *see* Attachment I of the program announcement as posted on the CDC Web site.

AR–1 Human Subjects Requirements
AR–2 Requirements of Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paper Work Reduction Act
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–17 Peer Review and Technical Reviews of Final Reports of Health Studies—ATSDR
AR–18 Cost Recovery—ATSDR
AR–19 Third Party Agreements—ATSDR
AR–22 Research Integrity

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements'.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd, Atlanta, GA 30341–4146. Telephone: 770–488–2700.

For business management and budget assistance, contact: Edna Green, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146. Telephone: 770–488–2743. e-mail address: *EGreen@cdc.gov.*

For program technical assistance, contact: Sherri Berger-Frank, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop E–28, Atlanta, Georgia 30333. Telephone: (404) 498–0522. E-mail address: *SBerger@cdc.gov*; or Scott Bowen, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop E–31, Atlanta, Georgia 30333. Telephone: (404) 498–3457. E-mail address: *msb4@cdc.gov.*

Dated: May 19, 2003.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–13378 Filed 5–28–03; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Centers for Medicare & Medicaid Services

[Program Announcement Nos. AoA–03–05 and CMS–2185–N]

Fiscal Year 2003 Program Announcement; Availability of Funds and Notice Regarding Applications

AGENCY: Administration on Aging, Centers for Medicare & Medicaid Services, HHS.

ACTION: Announcement of availability of funds and request for applications.

SUMMARY: The Administration on Aging (AoA) and the Centers for Medicare & Medicaid Services (CMS) announce that under this program announcement they will hold a competition for grant awards to be issued as cooperative agreements for up to sixteen (16) projects at a federal share of up to $800,000 over 3 (three) years.

Legislative authority: AoA's authority for these grants is under the Older Americans Act, Public Law 106–501 (Catalog of Federal Domestic Assistance 93.048, Title IV and Title II, Discretionary Projects). CMS' legislative authority for these grants is under section 1110 of the Social Security Act. Funding to CMS and Congressional language was provided in the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7). AoA and CMS are the designated HHS agencies with administrative responsibility for their respective portion for funding this joint effort. See Supplementary Information below for additional discussion of CMS' authority under section 1110.

Purpose of grant awards: The awards are to be used by states to develop Aging and Disability Resource Center programs that will provide citizen-centered ''one-stop shop'' entry points into the long term support system and will be based in local communities accessible to people who may require long term support. Resource Centers will serve individuals who need long term support, their family caregivers, and those planning for future long term support needs. They will also serve as

a resource for health and long term support professionals and others who provide services to the elderly and to people with disabilities.

Resource Centers supported under this program must, at a minimum, include the elderly population, and at least one of the following major target groups by the first quarter of the second year: (a) Individuals with physical disabilities, (b) individuals with serious mental illness, and/or (c) individuals with mental retardation/developmental disabilities.

These grants will be issued as cooperative agreements because AoA and CMS anticipate having substantial involvement with the recipients during performance of funded activities. The involvement may include collaboration, participation, or intervention in the funded activities. AoA and CMS will also be involved in the development and implementation of the funded projects by way of conducting a joint review of the applications and providing technical assistance, training, guidance and oversight throughout the project period. More specifically, letters of intent and applications may be submitted to AoA and CMS through the AoA ''single point of application'' address listed in this solicitation. AoA will ensure that all appropriate parties in both AoA and CMS receive the letter and application. AoA and CMS will make final decisions on the grant awards jointly. AoA and CMS project officers will jointly perform the day-to-day federal responsibilities. Grantees will be expected to keep in contact with AoA and CMS project officer staff on a regular basis. Grantees will also be expected to share all significant products that result from their projects with AoA and CMS.

Eligibility for grant awards and other requirements: Eligibility for grant awards (cooperative agreements) is limited to state agencies or instrumentalities of a state. Only one application per state will be accepted. The applicant agency must have the support and active participation of the Single State Agency on Aging and the Single State Medicaid Agency. Grantees are required to provide at least 5% of the project's total cost with non-Federal cash or non-financial recipient contribution (match) in order to be considered for the award. Non-financial recipient contributions may include the value of goods and/or services contributed by the Grantee (*e.g.*, salary and fringe benefits of staff devoting a percentage of their time to the grant not otherwise included in the budget or derived from federal funds). Recipient contributions must be included in the applicant's budget in Item 15 (Estimated Funding) on Standard Form 424A and described in the budget narrative/justification section of the application. The non-financial match requirement may also be satisfied if a third party participating in the grant makes an ''in-kind contribution,'' provided that the Grantee's contribution and/or the third-party in-kind contribution equals 5% of the total grant award (including all direct and indirect costs). Third-party ''in-kind contributions'' may include the value of the time spent by citizen task force members (using appropriate cost allocation methods to the extent that non-Federal funds are involved) who specifically contribute to the design, development and implementation of the grant.

Executive Order 12372 is not applicable to these grant applications.

Screening criteria: In order for an application to be reviewed, it must meet the following screening requirements:

1. Applications must be postmarked by midnight, July 28, 2003, or hand-delivered by 5:30 p.m. Eastern Time, on July 28, 2003, or submitted electrically by midnight, July 28, 2003. Electronic submissions must be sent to: *http://www.aoa.gov/egrants.*

2. The Project Narrative section of the Application must be double-spaced, on single-sided 8½″ × 11″ plain white paper with 1″ margins on both sides, and a font size of not less than 11.

3. The Project Narrative must *not* exceed 25 pages.

Review of applications: Applications will be evaluated against the following criteria: Problem Statement/Need for Assistance (5 points); Approach, Work Plan and Activities (25 points); Formative Learning and Information Management (10 points); Capabilities (10 points); Significance and Sustainability (15 points); Stakeholder Input and Partnerships (15 points); and Budget and Resources (20 points).

DATES: The deadline date for the submission of applications is July 28, 2003. Potential applicants are encouraged to submit a letter of intent to apply for a cooperative agreement not later than June 19, 2003. AoA and CMS will conduct an Applicants' Teleconference on June 12, 2003. Information regarding the time and call-in number for this open teleconference will be available on the AoA Web site at http://www.aoa.gov and on the CMS Web site at *http://www.cms.hhs.gov/newfreedom/default.asp.*

ADDRESSES: Application kits are available by writing to the U.S. Department of Health and Human Services, Administration on Aging, Center for Planning and Policy Development, Washington, DC 20201; by calling 202/357–3461; or online at http://www.aoa.gov/egrants or *http://www.cms.hhs.gov/newfreedom/default.asp.*

Applications may be mailed to the U.S. Department of Health and Human Services, Administration on Aging, Office of Grants Management, Washington, DC 20201, attn: Margaret Tolson (AoA–03–05).

Applications may be delivered to the U.S. Department of Health and Human Services, Administration on Aging, Office of Grants Management, One Massachusetts Avenue, NW, Room 4604, Washington, D.C. 20001, attn: Margaret Tolson (AoA–03–05).

If you elect to mail or hand deliver your application you must submit one original and two copies of the application; an acknowledgement card will be mailed to applicants. Instructions for electronic mailing of grant applications are available at *http://www.aoa.gov/egrants.*

SUPPLEMENTARY INFORMATION: All grant applicants are encouraged to obtain a D–U–N–S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number is free and easy to obtain from *http://www.dnb.com/US/duns_update/.*

These Aging and Disability Resource Center grants are a part of CMS' ''Real Choice Systems Change Grants for Community Living'' demonstration grants authorized under section 1110 of the Social Security Act. Funding and Congressional language was provided in the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7). In FY 2003, Congress appropriated an additional $40 million for Real Choice Systems Change Grants for Community Living. Congress also passed a 0.65% general reduction in the FY 2003 appropriation that has been distributed across Federal programs, including this appropriation, so the final amount available for grant awards will be slightly less than $40 million. The Administration on Aging (AoA), in collaboration with the Centers for Medicare & Medicaid Services (CMS), is inviting through this notice, proposals for a portion of this funding, totaling approximately $5 million dollars from CMS. A separate Notice of Funding Availability covering the CMS' other $35 million in Real Choice Systems Change Grants for Community Livingwill soon be published in the **Federal Register**.

Section 1110 (a)(1)(A) of the Social Security Act authorizes CMS make

''grants to States and public and other organizations and agencies for paying part of the cost of research or demonstration projects such as those * * * which will help improve the administration and effectiveness of programs carried on or assisted under the Social Security Act and programs related thereto * * *.'' CMS has restructured its efforts under § 1110 into eight themes. The Aging and Disability Resource Center Grants are part of CMS's Research and Demonstration efforts under Theme 5: Strengthening Medicaid, State Children's Health Insurance Program (SCHIP), and State Programs. This effort includes research and demonstrations on ways to improve access to and delivery of health care to the persons served by Medicaid. These Resource Center grants, to be awarded as cooperative agreements, are a part of the President's New Freedom Initiative. The New Freedom Initiative calls for the removal of barriers to community living for people with disabilities. CMS is the designated HHS agency with administrative responsibility for the Real Choice Systems Change Grant program. Because funding for this program appears as part of the agency's FY 2003 budget, all awards will be made to eligible entities before October 1, 2003.

We will not fund through these grants those efforts or activities that are already being funded under an existing Real Choice Systems Change Grant (funded in FY 2001 or FY 2002) or other grant funds. If a Grantee proposes to significantly expand an earlier-funded project, the applicant must specifically describe this expansion in its application. We also encourage states to seek private sector grant opportunities (*e.g.*, grants from foundations) to augment or coordinate with the Real Choice Systems Change Grants for Community Living.

Information Collection Requirements. The information collection requirements associated with this program announcement are under review by the Office of Management and Budget (OMB). A separate notice will be published in the **Federal Register** to solicit comments on this collection.

FOR FURTHER INFORMATION CONTACT: Kari Benson, U.S. Department of Health and Human Services, Administration on Aging, Center for Planning and Policy Development, Washington, DC, 20201, telephone: (202) 357–3461 or *Kari.Benson@aoa.gov.* Questions about the Real Choice Systems Change Grants for Community Living Program, and this notice, may also be directed to: Mary Guy, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, DEHPG/DCSI, Mail Stop: S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–2772, E-mail: *RealChoiceFY03@cms.hhs.gov.*

Dated: May 22, 2003.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. 03–13442 Filed 5–28–03; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–42–03]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Clinician's Management Approach to Children with Pharyngitis—New—National Center for Infectious Diseases (NCID), Centers for Disease control and Prevention (CDC). The purpose of this study is to determine factors associated with appropriate management of children with pharyngitis. We will characterize office laboratory methods currently used by clinicians to diagnose pharyngitis caused by group A streptococcus (GAS), including rapid antigen detection test (RADT) and throat cultures, and also assess clinicians' treatment approaches for pharyngitis.

The specific goals for this study on children with pharyngitis are:

1. To evaluate current diagnostic methods and treatment approaches for children with pharyngitis by primary care practitioners (pediatricians and family practitioners).

2. To identify factors associated with the use of appropriate laboratory methods by primary care practitioners.

3. To assess the treatment regimen including antimicrobial choices, length and goals of therapy.

4. To determine the impact of full implementation of CLIA on the performance of these tests in office settings.

The investigators will send out an eight-page questionnaire to a sample of 1000 members in each, the American Academy of Pediatrics and the American Academy of Family Practitioners. The survey includes questions on demographics; diagnostic approaches (including types of RADTs and cultures used); logistics in using the diagnostics (such as level of training of the personnel performing the tests, nature of quality control); clinicians' perception and understanding of the RADTs, including published sensitivity and specificity figures; and impact of CLIA (such as any change on the use of RADTs and culture). One month after the first mailing, each individual will be sent a second mailing to maximize the opportunity to complete the survey.

The study population consists of primary care physicians from pediatrics and family practice. These physicians will be from all areas of the United States and, therefore, from diverse geographic locations. The total burden is estimated to be approximately 400 hours.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hours)
Physicians	2,000	1	12/60

Thomas A. Bartenfeld,

Acting Deputy Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–13373 Filed 5–28–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–44–03]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Antineoplastic Drug Exposure: Effectiveness of Guidelines—New—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). Antineoplastic, chemotherapeutic, or cytostatic drugs are widely used in the treatment of cancer. These drugs possess mutagenic, teratogenic, and carcinogenic properties, cause organ damage, and affect reproductive function. Healthcare workers such as pharmacists and nurses who handle, prepare, and administer these drugs are at increased risk of adverse health effects from these agents, if exposed. The Occupational Safety and Health Administration (OSHA) developed guidelines for healthcare workers for the safe handling of antineoplastic drugs in 1986 and revised those guidelines again in 1995. However, recent studies suggest that the guidelines have not been effective in preventing exposure. A 1999 industrial hygiene evaluation of six cancer centers in the U.S. and Canada reported that 75% of the wipe test samples in the pharmacy were found to have detectable levels of antineoplastic drugs. Similar findings were reported in the Netherlands, which has similar guidelines. In addition, healthcare workers may assume that gloves designed for bloodborne pathogen protection will also prevent drug exposure which is often not the case. Since air concentrations of antineoplastic drugs in many of the studies have been low to non-detectable, it appears that the dermal route may be an important consideration for internal absorption.

Numerous studies, including those after the OSHA guidelines were revised in 1995, have demonstrated adverse health effects from healthcare workers' exposure to antineoplastic agents. The most common endpoints have been either markers of exposure, such as metabolites in the urine, or genotoxic markers, such as micronuclei, sister chromatid exchange, and chromosomal aberrations. Female reproductive adverse effects have also been shown to occur with healthcare workers' exposure to antineoplastic drugs. Not only have spontaneous abortion and miscarriage been reported, but changes in the menstrual cycle have been demonstrated as well. Based upon animal and human data, one study estimated that exposure to cyclophosphamide by healthcare workers increases the risk of leukemia cases by 17–100 new cases/million workers/10 years.

This project addresses the continuing concern of healthcare workers' exposure to antineoplastic agents. This is a multifaceted project that involves environmental sampling of the workplace and the collection of biological samples to determine how much of the agent is absorbed and if there are any early biological effects from that exposure. Biological measurements or biomarkers can detect effects of exposure long before a disease can be diagnosed. A questionnaire will be administered to determine confounders and other conditions that might affect exposure such as work history and work practices. This project will recruit oncology nurses, pharmacists, and pharmacy technicians and will be conducted in collaboration with the University of Maryland, the University of North Carolina, and the M.D. Anderson Cancer Center.

In the biological effects part of the study, the participant, after informed consent, will voluntarily provide blood and urine samples and respond to a questionnaire concerning medical history, work history, and work practices to identify study eligibility, past exposures, and confounders.

In the reproductive health part of the study and after informed consent, women will be asked to voluntarily give a daily urine sample for approximately 45 days and keep track of their menstrual cycle by entries into a diary. In addition, a short questionnaire will be given to each participant to determine eligibility for inclusion into the study and confounders of hormone analysis. By utilizing a battery of sensitive biomarkers, the effects of low-level chronic exposure to antineoplastic agents can be determined. Using the results of the proposed study, exposures can be minimized or eliminated before adverse health effects occur. Ultimately, the study will contribute to the prevention of occupational disease from antineoplastic drug exposure. The total annual burden for this data collection is 863 hours.

Survey	Number of respondents	Number of responses/respondent	Average burden/response (in hours)
Antineoplastic Handling Diary	75	1	10/60
Biological Effects Study Questionnaire	150	1	45/60
Reproductive Health Study Questionnaire	100	1	15/60
Reproductive Health Diary	100	42	5/60

Dated: May 21, 2003.

Thomas A. Bartenfeld,

Acting Deputy Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–13374 Filed 5–28–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–43–03]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of Effectiveness of NIOSH Publications (OMB Control No. 0920–0544)—Reinstatement without change—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). Through the development, organization, and dissemination of information, NIOSH promotes awareness about occupational hazards and their control, and improves the quality of American working life. Although NIOSH uses a variety of media and delivery mechanisms to communicate with its constituents, one of the primary vehicles is through the distribution of NIOSH-numbered publications. The extent to which these publications successfully meet the information needs of their intended audience is not currently known. In a period of diminishing resources and increasing accountability, it is important that NIOSH be able to demonstrate that communications about its research and service programs are both effective and efficient in influencing workplace change. This requires a social marketing evaluation of NIOSH products to measure the degree of customer satisfaction and their adoption of recommended actions.

The present project proposes to do this by conducting a survey of a primary segment of NIOSH's customer base, the community of occupational safety and health professionals. In collaboration with the American Association of Occupational Health Nurses (13,000 members), the American Industrial Hygiene Association (12,400 members), the American College of Occupational and Environmental Medicine (6,500 members), and the American Society of Safety Engineers (33,000 members), NIOSH will survey a sample of their memberships to ascertain, among other things: (1) Their perceptions and attitudes toward NIOSH as a general information resource; (2) their perceptions and attitudes about specific types of NIOSH publications (*e.g.*, criteria documents, technical reports, alerts); (3) the frequency and nature of referral to NIOSH in affecting occupational safety and health practices and policies; (4) the extent to which they have implemented NIOSH recommendations; and (5) their recommendations for improving NIOSH products and delivery systems. The results of this survey will provide an empirical assessment of the impact of NIOSH publications on occupational safety and health practice and policy in the United States as well as provide direction for shaping future NIOSH communication efforts. Respondents will have the option of responding by mail or electronically through the NIOSH Web site. The annual burden for this data collection is 200 hours.

Respondents	No. of respondents	No. of responses/ respondent	Average burden/response (in hrs.)
Occupational Safety and Health Professionals	600	1	20/60

Dated: May 22, 2003.

Thomas A. Bartenfeld,

Acting Deputy Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–13375 Filed 5–28–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–45–03]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Performance Evaluation Program for Rapid HIV Testing—New—Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC).

To support our mission of improving public health and preventing disease through continuously improving laboratory practices, the Model Performance Evaluation Program (MPEP), Division of Laboratory Systems, Public Health Practice Program Office, Centers for Disease Control and Prevention intends to provide a new HIV rapid testing performance evaluation program (HIV Rapid Testing MPEP). This program will offer external performance evaluation (PE) for rapid tests such as the OraQuick® Rapid HIV–1 Antibody Test, recently approved as a waived test by the U.S. Food and Drug Administration, and for other licensed tests such as the Abbott-Murex SUDS® HIV–1 Test. Participation in PE programs is expected to lead to improved HIV testing performance because participants have the opportunity to identify areas for improvement in testing practices. This program will help to ensure accurate testing as a basis for development of HIV prevention and intervention strategies.

This external quality assessment program will be made available at *no cost* (for receipt of sample panels) to

sites performing rapid testing for HIV antibodies. This program will offer laboratories/testing sites an opportunity for:

(1) Assuring that the laboratories/testing sites are providing accurate tests through external quality assessment;

(2) Improving testing quality through self-evaluation in a non-regulatory environment;

(3) Testing well characterized samples from a source outside the test kit manufacturer;

(4) Discovering potential testing problems so that laboratories/testing sites can adjust procedures to eliminate them;

(5) Comparing individual laboratory/testing site results to others at a national and international level, and consulting with CDC staff to discuss testing issues.

Participants in the MPEP HIV Rapid Testing program will be required to complete a laboratory practices questionnaire survey annually. In addition, participants will be required to submit results twice/year after testing mailed performance evaluation samples. The annual burden hours are estimated to be 175.

Forms	No. of respondents	Frequency of responses	Average burden/response (in hours)
HIV Rapid Testing Questionnaire	300	1	15/60
HIV Rapid Testing Results Booklet	300	2	10/60

Dated: May 21, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–13376 Filed 5–28–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03053]

Expansion of HIV Voluntary Counseling and Testing, Prevention of Mother-to-Child Transmission Studies, and HIV Surveillance in the Republic of South Africa; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2003 funds for a cooperative agreement program for the expansion of HIV Voluntary Counseling and Testing (VCT), Prevention of Mother-To-Child Transmission (PMTCT) services and HIV/AIDS surveillance in the Republic of South Africa. The Catalog of Federal Domestic Assistance number for this program is 93.941.

B. Eligible Applicant

Assistance will be provided only to the National Department of Health (NDOH) South Africa. The South Africa NDOH is the only appropriate and qualified organization to conduct a specific set of activities supportive of the CDC GAP's technical assistance to South Africa because:

1. The South Africa NDOH is uniquely positioned, in terms of legal authority, and commitment to the development and implementation of model VCT, PMTCT services and national HIV/AIDS surveillance in South Africa.

2. The NDOH already has established mechanisms to develop and implement VCT, PMTCT services and HIV/AIDS surveillance throughout all nine provinces enabling it to become engaged immediately in the activities listed in this announcement.

3. Guidelines and standards for VCT, PMTCT testing, counseling, training, referral services and HIV/AIDS surveillance have been developed and disseminated.

4. The purpose of the announcement is to build upon the existing framework of HIV prevention activities that the NDOH itself has developed or initiated.

5. The NDOH is mandated by the South African government to coordinate and implement HIV Prevention activities. This includes increased access to VCT, PMTCT and HIV/AIDS surveillance within South Africa.

6. No other institution has the capacity, legal mandate or expertise to accomplish these tasks.

C. Funding

Approximately $700,000 is available in FY 2003 to fund this award. It is expected that the award will begin on or before September 1, 2003 and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For technical questions about this program, contact: Jamie W. Legier, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: (770) 488–2635, E-mail address: *bzl3@cdc.gov.*

Dated: May 22, 2003.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–13379 Filed 5–28–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Refugee Unaccompanied Minor Placement Report (ORR–3), Refugee Unaccompanied Minor Progress Report (ORR–4)

OMB No.: 0970–0034

Description: The two reports collect information necessary to administer the Refugee Unaccompanied Minor Program. The ORR–3 (Placement Report) is submitted to the Office of Refugee Resettlement (ORR) by the service provider agency at initial placement and whenever there is a change in the child's status, including termination from the program. The ORR–4 (Progress Report) is submitted annually and records the child's progress toward the goals listed in the child's case plan.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–3	12	15	.417	75
ORR–4	12	60	.250	180

Estimated Total Annual Burden Hours: 255.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *rsargis@cf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, E-mail address: *lauren_wittenberg@omb.eop.gov*.

Dated: May 20, 2003.

Robert Sargis,

Reports Clearance, Officer.

[FR Doc. 03–13315 Filed 5–28–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

State Grants for Election Assistance for Individuals With Disabilities (EAID)

AGENCY: Administration on Developmental Disabilities (ADD), Administration for Children and Families, Department of Health and Human Services.

ACTION: Correction notice for: Notification of the Availability of Fiscal Year 2003 Funds under the Help America Vote Act, Public Law (Pub. L.) 107–252, title II subtitle D, part 2, section 261, Payments to States and Units of Local Governments to Assure Access for Individuals with Disabilities (42 U.S.C. 15421).

SUMMARY: The purpose of this notice is to correct errors that were printed in notice 68 FR 27816 on May 21, 2003. This notice (1) sets forth the requirements that must be met by a State seeking a payment under 42 U.S.C. 15421 of the Help America Vote Act of 2002 (HAVA); and (2) secures assurances from such a State related to conditions prior to receiving a payment.

EFFECTIVE DATE: May 29, 2003.

FOR FURTHER INFORMATION CONTACT: Contact Diann Winford at (202) 690–5963, *dwinford@acf.hhs.gov* or Carla Brown at (202) 690–8332, *crbrown@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: This notice is a correction of notice 68 FR 27816 that was printed on May 21, 2003. This notice amends errors in 68 FR 27816 concerning eligibility and closing dates. This notice should be used for funding opportunities available for fiscal year 2003 for State grants for election assistance for individuals with disabilities.

Part I: Introduction

The Help America Vote Act (HAVA), signed into law by President George W. Bush on October 29, 2002, contains several provisions that will enable an applicant to establish, expand, and improve access to and participation by individuals with the full range of disabilities (*e.g.*, blindness or visual impairment, deafness or hearing impairment, mobility-related, dexterity-related, emotional or intellectual) in the election process. The Catalog of Federal Domestic Assistance Number for this announcement is: 93.617.

Background

On February 20, 2003, in Division (N)—''Emergency Relief and Offsets,'' title I Election Reform, Disabled Voters Services, the Miscellaneous Appropriations Act, 2003, Pub. L. 108–7, Congress appropriated $13 million for States to operate the Election Assistance for Individuals with Disabilities (EAID) grant program. HAVA assigned responsibility for the EAID to the Secretary of Health and Human Services (the Secretary), who has assigned responsibility for carrying out this program to the Administration for Children and Families (ACF). Within ACF, the Administration on Developmental Disabilities (ADD) is responsible for the administration of the EAID grant program.

Eligible Applicants

As defined by section 901 of HAVA, States (including the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, and the Virgin Islands) are eligible to apply for grants under the EAID program. Grants are not available to local units of government directly from the Federal government in FY 2003 because Division (N)—''Emergency Relief and Offsets,'' title I Election Reform, Disabled Voters Services, the Miscellaneous Appropriations Act, 2003, Pub. L. 108–7, only appropriated funds for grants to States for FY 2003. Thus, while units of local government as well as States are eligible for funding under section 261 of the Help America Vote Act, the annual appropriations statute did not make funds available for grants to local governments.

Availability and Distribution of Funds

Congress appropriated $13,000,000 for payments to States for Federal fiscal year 2003. Payment amounts to States and Territories will be based on the relative size of the voting age population (*i.e.*, number of individuals 18 years of age or older as reported in the 2000 U.S. Census) of those States and Territories requesting payment, with the exception that no State or Territory applying for funds shall receive a payment of less than $100,000. *See* Table I for the amount reserved for each State and Territory, assuming all 55 States and Territories submit applications. If fewer than 55 States and Territories submit applications, those States and Territories applying for payment will receive a proportionately higher amount than that listed on Table I.

Any payment distributed shall remain available until expended.

In order to receive a payment a State must meet all of the requirements in part II of this notice. State governments receiving funds under this announcement will need to collaborate with local chief election officials and local units of government (including Indian tribes which are involved in

conducting elections for Federal offices) in determining where and how to spend funds.

The Federal government reserves the right to audit expenditure of funds received under this announcement pursuant to section 902 of the Help American Vote Act, 42 U.S.C. 15542 and 45 CFR 92.26, where applicable.

Use of Allotments

Section 261 of HAVA provides that funds be made available to:

a. Make polling places, including the path of travel, entrances, exits, and voting areas of each polling facility, accessible to individuals with the full range of disabilities (*e.g.*, blindness or visual impairment, deafness or hearing impairment, mobility-related, dexterity-related, emotional, or intellectual).

b. Provide the same opportunity for access and participation (including privacy and independence) to individuals with the full range of disabilities.

c. Train election officials, poll workers, and election volunteers on how best to promote the access and participation of individuals with the full range of disabilities in elections for Federal office.

d. Provide individuals with the full range of disabilities with information about the accessibility of polling places.

Part II: Application Requirements

All of the following conditions must be met by an applicant seeking a payment under 42 U.S.C. 15421 of the Help America Vote Act of 2002. An applicant must agree to these conditions in writing prior to receiving a payment by submitting an application. The conditions are to ensure that a payment will be used in compliance with HAVA. Payments must be used to pay for the activities described under part I, Use of Allotments.

Conditions

1. Some portion of the grant must be used for each of the following activities.

a. Make polling places, including the path of travel, entrances, exits, and voting areas of each polling facility, accessible to individuals with the full range of disabilities.

b. Provide the same opportunity for access and participation (including privacy and independence) to individuals with the full range of disabilities as for other voters.

c. Train election officials, poll workers, and election volunteers on how best to promote the access and participation of individuals with the full range of disabilities in elections for Federal office.

d. Provide individuals with the full range of disabilities with information about the accessibility of polling places.

2. In an application an applicant must provide:

a. The name of the State submitting the application.

b. The name of the Chief Election Official of the State submitting the application.

c. Contact person: Name, title, address, phone, fax, and e-mail address.

d. A description of what the applicant intends to do in each of the four categories of activities outlined under 1 above.

e. How much of the payment that the applicant intends to spend on each of the four categories of activities outlined in 1 above.

f. An assurance that six months after the ending of the fiscal year in which a payment is received, the Chief Election Official or his/her designee will submit a report to the Administration on Developmental Disabilities for the Secretary of Health and Human Services describing how the payment received was used with regard to the four categories of activities.

3. The application must include a completed SF 424, available at this Web address: *http://www.acf.hhs.gov/programs/add/announce.htm*.

4. The application must include the following certifications:

a. Anti-Lobbying Certification and Disclosure Form (45 CFR part 93).

b. Other Certifications: The signature on the application by the authorized official attests to the intent to comply with the following other certifications:

A. Certification Regarding Drug-Free Work Place (45 CFR part 76)

B. Debarment Certification (45 CFR part 76); and

C. Certification Regarding Environmental Tobacco Smoke.

5. The application must be signed by the Chief Election Official.

6. An application must be received no later than 4:30 p.m. e.d.t., on July 7, 2003, at the U.S. Department of Health and Human Services, ACF/Office of Grants Management, 370 L'Enfant Promenade, SW., Mail Stop 326F, Washington, DC 20447–0002, Attention: Joseph Lonergan. Hand-delivered applications should be delivered to Joseph Lonergan, Director, Division of Mandatory Grants, Office of Grants Management, 901 D Street, SW., 4th Floor East, Washington, DC (Telephone number: (202) 401–6603)). Any applications received after 4:30 p.m. on the deadline date will not be considered for payment.

Part III: Additional Information

Closing Date for Receipt of Assurances

The closing date for receipt of all applications is July 7, 2003.

Grant Administration Regulations

The regulations that govern the administration of these grants are: 45 CFR part 16—Procedures of the Departmental Grant Appeals Board; 45 CFR part 30—Claims Collection; 45 CFR part 76—Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants); 45 CFR part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services Effectuation of Title VI of the Civil Rights Act of 1964; 45 CFR part 81—Practice and Procedure for Hearings Under Part 80 of This Title; 45 CFR part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance; 45 CFR part 91—Nondiscrimination on the Basis of Age in HHS Programs or Activities Receiving Federal Financial Assistance; 45 CFR part 92—Uniform

Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments; and 45 CFR part 93—New Restrictions on Lobbying.

Reporting Requirements

Each grantee is required to submit annually a narrative report that describes how the funds are used in regard to the four categories of activities authorized under 42 U.S.C. 15461 of the Help America Vote Act of 2002. These reports are due no later than March 31 of each year. Reports must be mailed to: Administration on Developmental Disabilities, 200 Independence Avenue, SW., Room 300–F, Washington, DC 20201, Attention: Debbie Powell.

Expenditures under the EAID program are to be reported using a Financial Status Report (SF–269A). Grantees are required to submit annual financial reports (SF–269A) at the end of each 12 month grant period (September 1–August 31) until all funds have been expended. Funds under EAID are available until expended. Reports are due 90 days after the end of the grant period (November 30).

Submit the original SF–269A to ACF at the address below: Administration for Children and Families, Office of Administration, Division of Mandatory Grants, Attn: Joseph Lonergan, 370 L'Enfant Promenade, SW., Washington, DC 20447.

Notification Under Executive Order 12372

This program is covered under E.O. 12372, ''Intergovernmental Review of Federal Programs'' and 45 CFR part 100, ''Intergovernmental Review of Department of Health and Human Services Programs and Activities.'' However, since units of local governments are not funded in Fiscal Year 2003, the review and comment provisions of the Executive Order and part 100 do not apply for fiscal year 2003.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. 96–511), the application requirements contained in this notice have been approved by the Office of Management and Budget under control number 0348–0043.

TABLE I.—FY 2003 TENTATIVE ALLOCATIONS FOR ELECTION ASSISTANCE FOR INDIVIDUALS WITH DISABILITIES

State	FY 2003 tentative allotments
Alabama	185,341
Alaska	100,000
American Samoa	100,000
Arizona	209,686
Arkansas	109,029
California	1,371,756
Colorado	178,308
Connecticut	142,841
Delaware	100,000
District of Columbia	100,000
Florida	687,278
Georgia	335,237
Guam	100,000
Hawaii	100,000
Idaho	100,000
Illinois	511,102
Indiana	251,048
Iowa	122,161
Kansas	110,057
Kentucky	169,755
Louisiana	181,021
Maine	100,000
Maryland	219,527
Massachusetts	270,154
Michigan	409,083
Minnesota	202,382
Mississippi	115,296
Missouri	232,185
Montana	100,000
Nebraska	100,000
Nevada	100,000
New Hampshire	100,000
New Jersey	352,485
New Mexico	100,000
New York	795,936
North Carolina	339,029
North Dakota	100,000
Oregon	143,454
Ohio	471,600
Oklahoma	142,530
Pennsylvania	521,409
Puerto Rico	151,345

TABLE I.—FY 2003 TENTATIVE ALLOCATIONS FOR ELECTION ASSISTANCE FOR INDIVIDUALS WITH DISABILITIES—Continued

State	FY 2003 tentative allotments
Rhode Island	100,000
South Carolina	167,271
South Dakota	100,000
Tennessee	240,958
Texas	833,749
Utah	100,000
Vermont	100,000
Virgin Islands	100,000
Virginia	297,522
Washington	244,039
West Virginia	100,000
Wisconsin	185,426
Wyoming	100,000
Total	13,000,000

Dated: May 14, 2003.

Patricia A Morrissey,

Commissioner, Administration on Developmental Disabilities

[FR Doc. 03–13394 Filed 5–28–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 25 and 26, 2003, from 8:30 a.m. to 5 p.m.

Location: Marriott Washingtonian Center, The Ballrooms, 9751 Washingtonian Blvd., Gaithersburg, MD, 301–590–0044.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6758, or e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12538. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 25, 2003, the committee will discuss new drug application (NDA) 21–597, SEROSTIM (somatropin), Serono, Inc., for the treatment of short bowel syndrome in patients receiving specialized nutritional support. SEROSTIM therapy should be used in conjunction with optimal management of short bowel syndrome. On June 26, 2003, the committee will discuss NDA 21–525, PHOTOFRIN (porfirmer sodium), Axcan Scandipharm, Inc. Photodynamic therapy with PHOTOFRIN is indicated for the ablation of high-grade dysplasia in Barrett's esophagus among patients who refuse esophagectomy and who are in overall good health.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 16, 2003. Oral presentations from the public will be scheduled between 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 16, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Thomas H. Perez at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 22, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–13318 Filed 5–28–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA 93.918B, HRSA 03–093]

Title III Early Intervention Services Program (EISP)

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of fiscal year (FY) 2003 funds to be awarded under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Title III Early Intervention Services (EIS) Program for new proposals to support outpatient HIV early intervention and primary care services for low-income, medically underserved people in existing primary care systems. Grants will be awarded for a 3-year period.

Program Purpose: The purpose of this funding is to provide, on an ongoing outpatient basis, high quality, culturally competent, early intervention services/primary care to individuals with HIV infection. This is accomplished by increasing the present capacity and capability of eligible ambulatory health services entities. These expanded services become a part of a continuum of HIV prevention and care for individuals who are at risk for HIV infection or are HIV infected.

Program Requirements: As described in section 2651(b) of the Public Health Service Act, funded programs must provide the following services on an outpatient basis:

(A) Counseling individuals with respect to HIV disease;

(B) Testing individuals with respect to HIV disease, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from the disease;

(C) Referrals of individuals with HIV disease to appropriate providers of health and support services;

(D) Other clinical and diagnostic services regarding HIV disease and periodic medical evaluations of individuals with the disease; and

(E) Providing therapeutic measures as described in (B).

Funded programs must provide the proposed services directly and/or through formal agreements with public or nonprofit private entities. They may also provide services through agreements with private for-profit entities if such entities are the only available providers of quality HIV care in the area. A minimum of 50 percent of funds awarded MUST be spent on primary care services as described in items B–E above. No more than 10 percent of funds awarded may be spent on administration, including planning and evaluation.

Eligible Applicants: Applicants are limited to public entities or private nonprofit entities which meet the qualifications as described in section 2652(a) of the PHS Act, including (1) migrant health centers under section 329 or community health centers under section 330; (2) grantees under section 340 (regarding health services for the homeless; (3) grantees under section 1001 (regarding family planning) other than States; (4) comprehensive hemophilia diagnostic and treatment centers; (5) federally-qualified health centers under section 1905(1)(2)(B) of the Social Security Act; or (6) nonprofit private entities that provide comprehensive, primary care services to populations at risk of HIV disease. Faith-based and community-based organizations which meet these qualifications are eligible to apply.

Funding Priorities and/or Preferences: HRSA shall give preference to applicants in an area experiencing an increase in the burden of providing services regarding HIV disease, as described in section 2653 of the PHS Act. Measures of burden include the number and rate of increase of AIDS cases, other sexually transmitted diseases, tuberculosis and drug abuse; lack of availability of early intervention services; lack of availability of primary health services from providers other than the applicant; and the distance between such area and the nearest community that has an adequate level of availability of appropriate HIV-related services and the length of time required to travel such distance. Under section 2653(d), of the applicants who qualify for preference under this section, (1) HRSA shall give preference to applicants that will expend the grant under section 2651 to provide early intervention under such section in rural areas; and (2) HRSA shall give special consideration to areas that are underserved with respect to such services. These may include organizations serving communities of color that are highly affected by HIV/AIDS. Rural areas are located outside of urbanized areas and urban clusters as defined by the U.S. Census Bureau. Preferences, as described in the applications, will be considered after applications are scored.

Authorizing Legislation: The EIS program is authorized by section 2651(a) of the Public Health Service Act, as amended (42 U.S.C. 300ff–51).

Availability of Funds: Approximately $4 million is available for this initiative. HRSA expects to fund approximately 12–15 grants. The project and budget periods for approved projects will begin on or about September 1, 2003. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Application Deadline: Applications for this grant must be received in the HRSA Grants Application Center by close of business July 14, 2003. Applications shall be considered as meeting the deadline if they are either (1) received on or before the deadline date or (2) postmarked on or before the deadline date, and received in time for submission to the objective review panel. A legible dated receipt from a commercial carrier or the U.S. Postal Service will be accepted instead of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Grant applications postmarked after the deadline may be returned.

Where to Request and Send an Application: To obtain the official grant application kit (Form PHS–5161–1) and program guidance materials for this announcement call the HRSA Grant Application Center at 877–477–2123 and request the OMB Catalogue of Federal Domestic Assistance number 93.918B, HRSA 03–093, EISP. In fiscal year 2003 HRSA will begin accepting grant applications online. Please refer to the HRSA Grants Schedule at *http://www.hrsa.gov/grants/* for more information.

ADDRESSES: All applications should be mailed or delivered to HRSA Grant Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland 20879. Grant applications sent to any other address will be returned. The Internet address for HAB is *http://www.hab.hrsa.gov/.*

FOR FURTHER INFORMATION CONTACT: Additional information related to the program may be requested from the Division of Community Based Programs, HIV/AIDS Bureau, HRSA, 5600 Fishers Lane Room 7A–30, Rockville, Maryland 20857. The telephone number is (301) 443–0493; and the fax number is (301) 443–1884.

SUPPLEMENTARY INFORMATION: Applications will be reviewed by an objective review committee. The review criteria will include: (1) Justification of

need, (2) organizational capabilities and experience, (3) coordination and linkage with other HIV programs, (4) adequacy of scope of work for providing early intervention services, (5) work plan, (6) program evaluation, (7) appropriateness and justification of budget, and (8) adherence to program guidance.

There is no matching requirement for this program.

Public Health System Reporting Requirements: Under these requirements (approved under OMB No. 0937–0195), a community-based, non-governmental applicant must prepare and submit a Public Health System Impact Statement to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date. This statement must include (1) a copy of the face page of the application (SF424) and (2) A summary of the project, not to exceed one page, which provides a description of the population to be served; a summary of the services to be provided; and a description of the coordination planned with the appropriate State and local health agencies.

Executive Order 12372: This program has been determined to be a program which is subject to the provision of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, as implemented by 45 CFR part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application packages to be made available under this notice will contain a listing of States that have chosen to set up such a review system and will provide a single point of contact (SPOC) in the States for review. Applicants (other than federally-recognized Indian tribal governments) should contact their State SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contract the SPOC of each affected State. The due date for the State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to ''accommodate or explain'' for State process recommendations it receives after that date. (*See* part 148, Intergovernmental Review of Public Health Service Programs under Executive Order 12372 and 45 CFR part 100 for a description of the review process and requirements).

Dated: May 8, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–13319 Filed 5–28–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[HRSA 03–104]

State Planning Grants (SPG)

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of approximately $15 million to provide supplemental grants to States that have previously received planning grants in order to assist such States in continuing their data gathering, analysis, and planning processes, and to support approximately ten new State grants for the development of approaches to provide access to health insurance coverage for all State residents. This funding has been appropriated under the Fiscal Year (FY) 2003 HHS Appropriations Act.

In FY 2003, HRSA, through its State Planning Grants (SPG) Program, will accept applications from (1) States which have previously received SPG grant funds to enhance and refine activities already conducted with an average grant award of approximately $150,000 and (2) States which have never received SPG grant funds with a grant award ranging from $800,000 up to $1.2 million. These grants will be used, over a 12-month period, (1) to enhance and refine work already conducted with previous SPG grant funds; and (2) for new States to identify the characteristics of the uninsured within the State and develop approaches for providing all uninsured persons with access to health coverage. States will be expected to design approaches that provide affordable health insurance benefits similar in scope to the Federal Employees Health Benefit Plan, Medicaid, coverage offered to State employees, or other similar quality benchmarks. Each State receiving such grants must submit the study and analysis results in the form of a report to the Department that identifies the characteristics of the uninsured within the State and proposals for providing them with access to health insurance coverage. Together, these reports will provide additional data about the characteristics of the uninsured generally and potential models for other States seeking to provide comprehensive coverage.

Where to Request and Send an Application: To obtain the official grant application kit (PHS Form 5161–1) contact the HRSA Grants Application Center at, 1–877–477–2123, fax: 1–877–477–2345, e-mail: *hrsagac@hrsa.gov* and request the Office of Management and Budget Catalog of Federal Domestic Assistance Number #93.256, Program Code SPGP, and HRSA #03–104. Please mail completed applications to the HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879.

It is anticipated that there will be a pre-application workshop in the Washington, DC area. For more information concerning this workshop, contact the SPG Office at 301 443–2309.

Application Deadline: Applications for grants from States which have previously received SPG grant funds must be received in HRSA's Division of Grants Management Operations by close of business July 14, 2003. Applications for grants from States which have never received SPG grant funds must be received in the HRSA Grants Application Center by close of business July 28, 2003. Applications shall be considered as meeting the deadline if they are received on or before the deadline date.

FOR FURTHER INFORMATION CONTACT: For further information contact Ms. Judy Humphrey, Health Resources and Services Administration, Parklawn Building, Room 16C–17, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 443–2309, Fax: (301) 443–1267, Email: *JHumphrey@hrsa.gov*.

SUPPLEMENTARY INFORMATION: In 2001, 41.2 million people in the United States did not have health insurance. This is roughly 1 out of every 6 non-elderly Americans. Of these, 24.2 million were employed—19.0 million worked full time and 5.2 million worked part-time. Nationally, over 8.5 million children or 11.7 percent are uninsured. Every year, approximately a million Americans lose their health coverage. There is considerable public and private support for examining and implementing new models for providing access to affordable health coverage.

Many States are currently experiencing fiscal challenges. However, covering the uninsured continues to be a priority for many States. Every State has responded to the opportunity provided by the State Children's Health Insurance Program

(SCHIP) to implement a program that provides health insurance coverage for uninsured low-income children. Many States have also expanded Medicaid coverage to uninsured children and adults, using existing options, such as section 1115 waiver authority, as well as increased flexibility under welfare reform to cover working parents. Eight States have used the administration's new Health Insurance Flexibility and Accountability (HIFA) initiative, a section 1115 demonstration approach announced in August 2001 that emphasizes coverage expansions. Some States are working towards enhancing coordination of publicly-funded health programs, such as health departments and community health centers. States have also undertaken activities that seek to expand insurance coverage through mechanisms other than Federally-financed programs (*e.g.*, high risk pools and insurance market changes).

The private sector has expressed an interest in supporting States' efforts to expand coverage for the uninsured. The Robert Wood Johnson Foundation has implemented the State Coverage Initiatives (SCI), a major technical assistance endeavor that will build on the successes and lessons learned in its earlier States Initiatives in Health Care Reform. The program seeks to improve the practical capacity of State governments in their quest to decrease the number of uninsured Americans and has an emphasis on policy development and technical assistance. The SCI Program provides resources for technical assistance that States can use to analyze data, diagnose problems, identify solutions, and develop new strategies and policies. It offers small policy planning grants and for a few States, larger scale demonstration grants.

In March 2003, a group of health foundations and national organizations, including the Robert Wood Johnson Foundation, The California Endowment, and the W.K. Kellogg Foundation, conducted an educational and advertising campaign entitled *Cover the Uninsured Week* in an effort to sensitize the public and opinion leaders to the plight of the more than 41 million Americans who lack health insurance. The unprecedented series of national and local activities was designed to raise public awareness of the plight of more than 41 million uninsured Americans; demonstrate broad support for action on the issue; generate significant media attention to the issue, both nationally and in key communities across the country; encourage other national organizations to join The Robert Wood Johnson Foundation and 18 partner organizations in an effort to increase attention to the issue; and create a single rallying point for groups and individuals working to extend health care coverage to the uninsured.

At the Federal level, the HHS is committed to assisting States as they examine their options for expanding health insurance benefits. By providing State planning grants, the HRSA SPG Program intends to encourage States to provide access to affordable health insurance coverage for all its citizens. Each grantee State will receive resources for necessary planning as well as assistance in researching and identifying policy options. Together, the results of each State's analysis of its uninsured population and its proposals for providing these individuals with access to health insurance coverage will provide additional data about the characteristics of the uninsured generally and present models for other States seeking to provide such comprehensive coverage.

SPG shares some of the same goals as and focus of the Robert Wood Johnson Foundation's State Coverage Initiatives and the Health Policy Studies Division of the National Governors' Association Center for Best Practices. Thus, whenever possible, SPG will coordinate its efforts with activities of these programs to share information about insurance trends, best practices, data and analyses, and technical assistance.

State Planning Grants for States Which Have Previously Received SPG Grant Funds

Program Purpose

The purpose of supplemental SPG grants for States which have previously received SPG grant funds is to assist such States in continuing their data gathering, analysis and planning processes. The supplemental grant will allow States to enhance, refine, and update the work of their initial SPG award to plan to provide all uninsured persons with health coverage. Not only will the grantee State benefit from further analyses, but by submitting a summary of these analyses and proposed plan at the end of the supplemental grant period in an addendum report to the Department, other States may learn about successful or innovative ways to provide access to coverage. In addition, HHS will have the opportunity to review these reports and gain insight into effective methods of supporting such endeavors.

Program Goal

The overarching SPG goal is to encourage States to provide access to health insurance coverage to all uninsured citizens by providing the resources needed to develop successful plans and to provide a number of data collection and planning strategies, along with viable insurance expansion options to consider. The immediate goal of SPG for those States which have previously received SPG grant funds is to assist such States in continuing their data gathering, analysis and planning processes for programs that provide health insurance coverage to all uninsured citizens in the State through expanded State, Federal, and private partnerships.

Program Description

The approximately $15 million in available funding for all SPG grant activities has been appropriated under the FY 2003 Labor-HHS Appropriations Act. The HRSA, Office of Special Programs, SPG Program, will oversee the program. The program will provide supplemental grants to States which have previously received SPG grant funds, whose size will vary, with an average grant award of approximately $150,000 for the 31 States and 1 Territory which have previously received SPG grant funds. The total amount of funds set aside for supplemental grants is approximately $4.0 million.

During FY 2003, SPG will support 1-year supplemental planning grants to States which have previously received SPG grant funds to (1) as applicable, further collect and analyze data that describe the characteristics of their uninsured and assist in the design of approaches to provide access to affordable coverage, (2) enhance, refine, and/or update the design of a program that would provide all uninsured with access to insurance benefits similar in care to State employee coverage, Federal Employees Health Benefit Plan, Medicaid or other similar quality benchmarks, through a State, Federal, and private partnership, (3) prepare an addendum report to the Department describing the findings of the new activities and how they relate to previously conducted activities, and (4) within 30 days after the end of the grant period, provide an addendum report to the Department describing any changes to original proposals for an expanded State, Federal, and private partnership to cover all of their uninsured.

The successful State applicant for supplemental SPG grant funds will demonstrate a continued commitment to reducing its uninsured population; will demonstrate a continued commitment by its Executive Branch to studying the possibilities for providing health

insurance coverage to all uninsured; and will present a comprehensive description and justification for the activities proposed to be conducted with supplemental SPG grant funds. Activities may include, but are not limited to additional data collection, analysis of that data, use of the analyses to enhance, refine, and update an approach or approaches for covering all uninsured, and a refined strategy for implementing and funding that approach. The successful applicant will continue to work with all appropriate health-related State agencies, including the Medicaid agency, the budget office, and other relevant departments (*e.g.*, insurance, public health, human services, mental health and substance abuse, and aging). The State applicant should also demonstrate continued communication with the health committees in the State legislature about the proposal. Formal collaboration should continue to exist with private sector organizations (including both business and the health care provider communities), consumer groups, and researchers.

Eligible Applicants

All States which have previously received State Planning Grant funds are eligible to apply for supplemental funds to assist such States in continuing their data gathering, analysis and planning processes to enhance and refine existing plans. Only one agency or entity may apply per State and it must be a part of the State government. A letter from the Governor authorizing this entity or agency to apply for the supplemental funds should accompany the application, unless the request is from the entity which was awarded the original grant.

Funding Criteria

Review criteria that will be used to evaluate applications from States which have previously received State Planning Grant funds include the extent to which the application provides:

A detailed description of activities and results that have been accomplished with previously received SPG grant funds.

A detailed description of the activities proposed to be conducted with the supplemental funds and how these activities will enhance and build upon the activities already completed and as applicable, be integrated with the activities yet to be completed, with the previously received SPG grant funds.

A description of the anticipated results of these proposed tasks and how they will expand health insurance coverage options to the uninsured.

A description of the technical capacity, resources, and collaboration needed to successfully carry out the proposed activities and provide the required report to the Department.

An accountable management and budget plan with time lines, demonstrating readiness of the State government to conduct the proposed supplemental activities which will result in new or refined approaches to providing access to coverage and determine strategies for implementing and funding such approaches. States should provide an explanation of how they will contract for needed technical assistance, if necessary. For those States with existing State Planning grants, the integration of proposed work with work not yet completed is required.

A description of how the proposed supplemental activities will augment earlier efforts to the report to the Department.

Report Contents

The grant funding provided to States which have previously received SPG grant funds, will assist States to enhance and refine models for providing access to health insurance coverage for all citizens of the State. Each grantee State who receives supplemental SPG grant funds, will be required to prepare an addendum report to the Department that describes the results of the supplemental activities and how these activities have augmented earlier efforts.

Use of Grant Funds

Funding provided through this program may not be used to substitute for or duplicate funds currently supporting similar activities. In addition, grant funds may not be used to support construction, renovation or modernization costs. However, grant funds may support costs such as project staff salaries, consultants, project-related travel, project evaluation, limited equipment and software purchases or leases, and coordinating project-related meetings.

Expected Results

The implementation of supplemental State Planning grant funds is expected to result in the further development of a plan that the State might subsequently implement to provide health insurance coverage to all citizens of the State. In addition, the grantee States will provide information about data collection activities, partnerships, and options that other States may draw from in their efforts to expand health insurance coverage.

State Planning Grants for States Which Have Never Received SPG Grant Funds

Program Purpose

The purpose of SPG is to have each new grantee State develop a plan or propose options that would ensure every citizen in that State access to affordable health insurance benefits similar in scope to the Federal Employees Health Benefit Plan, Medicaid, benefits offered to State employees or other similar quality benchmarks. Not only will the grantee State benefit from its analysis, but by submitting a summary of this analysis and proposed plan at the end of the grant period in a report to the Department, other States may learn about successful or innovative ways to provide access to coverage. In addition, HHS will have the opportunity to review these reports and gain insight into effective methods of supporting such endeavors.

Program Goal

The overarching SPG goal is to encourage States to provide access to health insurance coverage to all uninsured citizens by providing the resources needed to develop successful plans and to provide a number of data collection and planning strategies, along with viable insurance expansion options to consider. The immediate goal of SPG is to assist States as they collect and analyze data, develop coverage options or design programs that provide health insurance coverage to all uninsured citizens in the State through expanded State, Federal, and private partnerships.

Program Description

The approximately $15 million in available funding for all SPG grant activities has been appropriated under the FY 2003 Labor-HHS Appropriations Act. The HRSA, Office of Special Programs, State Planning Grants Program, will oversee the program. Up to 10 new awards are anticipated which will vary in size, with a grant award ranging from $800,000 up to $1.2 million. The total amount of funds for new grants is approximately $10.0 million.

During FY 2003, SPG will support one-year planning grants to States to (1) collect and analyze data that describe the characteristics of their uninsured and assist in the design of approaches to provide access to affordable coverage, (2) design a program that would provide all uninsured with access to insurance benefits similar in care to State employee coverage, Federal Employees Health Benefit Plan, Medicaid or other similar quality benchmarks, through a

State, Federal, and private partnership, (3) prepare a report to the Department describing these findings, and (4) within 30 days after the end of the grant period, provide the report to the Department describing proposals for an expanded State, Federal, and private partnership to cover all of their uninsured.

The successful State applicant will have a demonstrated commitment to reducing its uninsured population; will demonstrate commitment by its Governor and Executive Branch to studying the possibilities for providing health insurance coverage to all uninsured; and will present a comprehensive proposal for the kinds of data to be collected, analysis of that data, use of the analyses to create an approach for covering all uninsured, and a strategy for implementing and funding that approach. The successful applicant will work with all appropriate health-related State agencies, including the Medicaid agency, the budget office, and other relevant departments (*e.g.*, insurance, public health, human services, mental health and substance abuse, and aging). If possible, the applicant should demonstrate communication with the health committees in the State legislature about the proposal. Formal collaboration must exist with private sector organizations (including both business and the health care provider communities), consumer groups, and researchers.

We are looking for applicants with a clear commitment to the goal of providing coverage to all uninsured and an operational plan for using these planning grants to help achieve that goal. As such, funded State planning grants will contain these common elements:

A goal of providing access to affordable health insurance coverage to all citizens in the State—Access to affordable coverage for this grant program means that individuals or families have the opportunity to purchase health insurance coverage or participate in a program that provides adequate benefits at an affordable cost. States may ensure ''affordability'' by determining cost-sharing based on the beneficiary's income level and applying a sliding scale related to income, or implementing other cost-sharing protections such as spending caps. For example, in non-Medicaid SCHIP programs, for children in families with income levels above 150 percent of the Federal poverty line, cost-sharing may be imposed on a sliding scale related to income, but the total annual aggregate cost-sharing for all targeted low-income children in the family cannot exceed 5 percent of the family's annual income.

Citizens of the State—If Federal funds are proposed to be used, States should plan their coverage options based on existing Federal eligibility criteria for participation in the Medicaid, SCHIP, and Medicare programs. States may use State funds or other resources to cover non-citizen residents.

Commitment to eliminating the number of uninsured—Grantee States must demonstrate prior efforts, whether or not approved by their State Legislatures, to reduce their number of uninsured through program expansions, data collection activities to support further expansions and/or other activities demonstrating a commitment to providing increased access to health insurance for its citizens.

Collaboration among State, Federal, and private partners—Grantee States should build upon current collaborations among State, Federal, and private partners for expanding health insurance coverage to all citizens within the State. States are encouraged to consult with Tribal governments, where appropriate. These collaborations should be formal and should include the leadership of public and private partners.

Capacity for data collection and analysis—Grantee States should demonstrate data collection and analytical capacity or a detailed plan for acquiring this technical assistance, including a commitment from the agency/organization to provide this technical assistance. States are encouraged to work with the many existing Federal and State data collection activities, as well as ongoing efforts in the private, non-profit sector.

Eligible Applicants

Eligibility for new grants is limited to States which have never received SPG grant funds with only one application per State permitted. Each Governor is asked to designate the entity or agency responsible for preparing the State's grant application. The entity or agency must be a part of the State government. A letter from the Governor authorizing this entity or agency to prepare the State's application should accompany the application.

Funding Criteria

Review criteria that will be used to evaluate applications from States which have not previously received State Planning Grant funds includes:

Evidence of commitment by the Governor, State agencies, and public and private health care providers to provide coverage to all uninsured.

Evidence of prior data collection and analysis resulting in efforts to expand coverage to the uninsured.

Evidence of meaningful collaboration between the agencies and constituencies in the public and private sectors necessary to successfully complete the analysis and submit the required report to the Department.

A demonstrated understanding of the technical capacity, resources, and collaboration necessary to successfully carry out the proposed analysis and provide the required report to the Department.

An accountable management and budget plan with time lines, demonstrating readiness of the State government to conduct the data collection, analyze the data, develop approaches to providing access to coverage, and determine strategies for implementing and funding such approaches. States should provide an explanation of how they will contract for needed technical assistance, if necessary.

Report Contents

The new grant funding provided to States, which have not previously received SPG grant funds, will assist States to develop models for providing access to health insurance coverage for all citizens of the State. As a result, each grantee State will prepare a report to the Department that provides:

A detailed plan for data collection and analysis, upon which the State will base its design for covering its uninsured.

Its strategy for gaining collaboration and consensus among State, Federal, and private partners on options to expand health insurance coverage to all citizens.

Options for expanding health insurance coverage through State, Federal, and private partnerships. The following options and issues are areas that the State may wish to address, if relevant in the State. These options and issues include (1) targeting expansion groups such as parents of SCHIP children, young adults ages 19–20, and early retirees; (2) delivery systems; (3) administration; (4) outreach; (5) eligibility levels; (6) eligibility determination process; (7) enrollment process; (8) marketing plan; (9) coverage and benefits (similar to State, Federal employees, Medicaid, and other credible coverage); (10) portability; (11) cost-sharing (co-pays, premiums); (12) integration with existing public and private programs (*e.g.*, Medicaid, Medicare, and SCHIP coverage, State programs, projects proposed through the Community Access Program); (13) plans

for studying or avoiding crowd-out-interaction with employer-sponsored insurance; (14) cost-containment; (15) ensuring quality; (16) ensuring access; (17) data collection; (18) audits; (19) program budget; (20) program evaluations; (21) funding; (22) maintenance of effort; (23) necessary waivers (under existing program authority); (24) necessary State or Federal legislative changes (not under current authority); and (25) private sector options (*e.g.*, high risk pools, employer options, market reforms). States that propose or prepare waivers or State plan amendments (*e.g.*, Medicaid waivers, SCHIP amendments) as a result of their grant activities must submit their requests through existing review processes established by the Centers for Medicare and Medicaid Services.

Use of Grant Funds

Funding provided through this program may not be used to substitute for or duplicate funds currently supporting similar activities. In addition, grant funds may not be used to support construction, renovation or modernization costs. However, grant funds may support costs such as project staff salaries, consultants, project-related travel, project evaluation, limited equipment and software purchases or leases, and coordinating project-related meetings.

Expected Results

The implementation of State Planning grants is expected to result in the development of a plan that the State might subsequently implement to provide health insurance coverage to all citizens of the State. In addition, the grantee States will provide information about data collection activities, partnerships, and options that other States may draw from in their efforts to expand health insurance coverage.

Paperwork Reduction Act: Should any data collection activities fall under the purview of the PRA, OMB clearance will be sought. PHS Form 5161.1—CFDA 93.256.

Dated: May 22, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–13392 Filed 5–28–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Customer Satisfaction with Educational Programs and Products of the National Cancer Institute

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed collection—Title: Customer Satisfaction with Educational Programs and Products of the National Cancer Institute.

Type of Information Collection Request: NEW.

Need and Use of Information: The Office of Education and Special Initiatives (OESI) of the National Cancer Institute (NCI) is responsible for the design, implementation, and evaluation of education programs over the entire cancer continuum, including prevention, screening, diagnosis, treatment, survivorship, and palliative care; it also manages NCI initiatives that address specific challenges in cancer research and treatment. To help ensure the relevance, utility, and appropriateness of the many educational programs and products that OESI and NCI produce, OESI intends to collect information on customer satisfaction with those products through customer satisfaction surveys. By obtaining information from customers on the extent to which materials satisfy their needs, OESI and NCI will be able to systematically establish and follow a feedback loop that provides useful information to revise and enhance educational programs and products so that they attain maximum relevance, utility, appropriateness, and impact. Data will be collected through various means, including telephone, mail, in-person, and web-based surveys.

Frequency of Response: On occasion.

Affected Public: Individuals or households, organizations involved in providing health care services.

Type of Respondents: Health care consumers of NCI educational programs or products, including cancer patients and families, health care professionals, cancer control planners, and policymakers.

The estimated annual burden hours are as follows:

Product	Average sample size	Estimated number of responses per respondent	Average duration (hours)	Estimated total burden requested (hours)
40 different products	450	1	0.1	1,800

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Lenora Johnson, Acting Director, Office of Education & Special Initiatives, Branch Chief, Patient & Family Education National Cancer Institute, 6116 Executive Blvd., Ste. 202, Room 2029, Bethesda, MD 20892–8334, Non-toll free (301) 451–4056.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: May 19, 2003.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 03–13365 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group Subcommittee H—Clinical Groups.

Date: July 6–9, 2003.

Time: 5 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Deborah R. Jaffe, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8038, MSC 8328, Bethesda, MD 20892, (301) 496–7721, *dj86k@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: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13351 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Eye Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Eye Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Eye Institute.

Date: July 14–15, 2003.

Time: July 14, 2003, 8 a.m. to 5 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

Time: July 15, 2003, 8 a.m. to 12 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Miller S. Sheldon, PhD., Scientific Director, National Institutes of Health, National Eye Institute, Bethesda, MD 20892. (301) 451–6763.

Information is also available on the Institute's/Center's Home page: *http://www.nei.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13360 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel, Centers of Excellence in Chemical Methodologies and Library Development.

Date: June 22–23, 2003.

Time: 8 PM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Laura K Moen, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN–12, Bethesda, MD 20892, 301–594–3998, *moenl@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13348 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel Phase II—Topic 017: Transdermal, Non-Invasive Monitoring of Medication Ingestion.

Date: June 12, 2003.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate contact proposals.

Place: NIAA, Wiilco Bldg. Rm 409, 6000 Executive Blvd., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, PhD., Scientific Review Administrator, Extramural Project Review Branch, Office of Scientific Affair, National Institute on Alcohol, Abuse and Alcoholism, 6000 Executive Blvd, Suite 409, Bethesda, MD 20892–7003 (301) 443–2926, *skandasa@mail.nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel RFA AA03–009 Alcohol Abuse and HIVE/AIDS in Resource Poor Societies.

Date: August 12, 2003.

Time: 8 am to 6 pm.

Agenda: To review and evaluate grant applications.

Place: Double Tree, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mahadev Murthy, PhD., Scientific Review Administrator, Extramural Project Review Branch, Office of Scientific Affair, National Institute on Alcohol Abuse and Alcoholism, 6000 Executive Blvd., Suite 409, Bethesda, MD 20892–7003, (301) 443–2860.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HSS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13349 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel Hormonal Signals that Regulate Ovarian Differentiation.

Date: June 16, 2003.

Time: 9 AM to 3 PM.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5E03, Bethesda, MD 20892, (301) 435–6884.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13350 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group Maternal and Child Health Research Subcommittee.

Date: June 16–17, 2003.

Time: 9:30 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13352 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group Population Research Subcommittee, Demographic and Behavioral Sciences (DBS) Review Committee.

Date: June 19–20, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Blvd., Rm. 5E01, MSC 7510, Bethesda, MD 20892, (301) 435–6684.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13353 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group Mental Retardation Research Subcommittee.

Date: June 16–17, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Park Hyatt Washington Hotel, 24th at M Street, NW., Washington, DC 20037.

Contact Person: Norman Change PhD, Scientific Review Administrator, National Institute of Child Health and Human Development, National Institutes of Health, PhS, DHHS, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13354 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Regional Centers of Excellence of Biodefense and Emerging Diseases Research—West.

Date: June 11–13, 2003.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center. 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Katherine L. White, PhD, Scientific Review Administrator, Scientific Review Programs, NIAID/DEA, 6700B Rockledge Drive, Bethesda, MD 20892, 301–496–2550, *kwhite@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Regional Centers of Excellence in Biodefense and Emerging Diseases Research—East.

Date: June 18–20, 2003.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Nancy B. Saunders, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2217, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, *ns120v@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13355 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIDCR Special Grants Review Committee, Review of R03's, Ts, and Fs.

Date: June 19–20, 2003.

Time: 8 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lynn M. King, PhD, Scientific Review Administrator, Scientific Review Branch, 45 Center Dr., Rm 4AN–38K, National Institute of Dental & Craniofacial Research, National Institutes of Health, Bethesda, MD 20892–6402, (301) 594–5006.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13357 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel. ''Development of Science Education Materials'' (Topic 029).

Date: June 4, 2003.

Time: 1:30 PM to 3:30 PM.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Eric Zatman, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547, (301) 435–1438.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS).

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13359 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Muscular Dystrophy Coordinating Committee; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the first meeting of the Muscular Dystrophy Coordinating Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the contact person listed below in advance of the meeting.

Name of Committee: Muscular Dystrophy Coordinating Committee.

Date: July 1, 2003.

Time: 9 a.m. to 3:30 p.m.

Agenda: The purpose of this first meeting of the Muscular Dystrophy Coordinating Committee (MDCC) is to inform committee members about the role of the MDCC, to learn about the collective experience on the committee, and to design a strategy for developing a research and education plan on muscular dystrophy. Committee members will discuss the activities at their agency or organization relevant to muscular dystrophy research and education and will also present their ideas and expectations for the MDCC.

Place: Democracy II, 6707 Democracy Blvd., Room 701, Bethesda, Maryland 20892.

Contact Person: Lorraine Fitzsimmons, Executive Secretary, Muscular Dystrophy Coordinating Committee, Director, Office of Science Policy and Planning, National Institute of Neurological Disorders and Stroke, NIH, 31 Center Drive, Room 8A03, MSC 2540, Bethesda, MD 20892, Email: *fitzsiml@ninds.nih.gov*, *Phone:* (301) 496–9271.

(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: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13361 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, ''Comprehensive International Program of Research on AIDS'' (CIPRA).

Date: June 20, 2003.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Gerald L. McLaughlin, PhD., Scientific Review Administrator, Scientific Review Program, National Institute of Allergy and Infectious Diseases, DEA/NIH/DHHS, 6700–B Rockledge Drive, MSC 7616, Room 2212, Bethesda, MD 20892–7616, (301) 436–7465, *gm145a@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 21, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13362 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice

is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, ''Web-based Games to Support Drug Abuse'' (Topic 034).

Date: June 5, 2003.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547, (301) 435–1439.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: May 21, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13363 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Enhancing HIV Vaccine Efficacy in High-Risk Drug Users.

Date: June 23, 2003.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Arlington, 1325 Wilson Boulevard, Arlington, VA 22209.

Contact Person: Eliane Lazar-Wesley, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547. 301–451–4530.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Immunotherapy for Addiction Treatment: SBIR/STTR Initiative.

Date: June 30, 2003.

Time: 10 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Khursheed Asghar, PhD, Chief, Basic Sciences Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547. (301) 443–2620.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS.)

Dated: May 21, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13364 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel.

Date: June 12, 2003.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Merlyn M. Rodrigues, MD, PhD, Medical Officer/SRA, National Library of Medicine, Extramural Programs, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13347 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosures of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Mitochondria In Cancer Therapy.

Date: May 27, 2003.

Time: 11 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 SSS9 40P: Program Project: National Biomedical Computation Resource.

Date: June 15–17, 2003.

Time: 3 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Hotel, 2000 Second Street, Coronado, CA 92118.

Contact Person: Bill Bunnag, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5124, MSC 7854, Bethesda, MD 20892–7854, 301–435–1177, *bunnagb@csr.nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Molecular, Cellular and Developmental Neurosciences 2.

Date: June 16–17, 2003.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

Contact Person: Gillian Einstein, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892, 301–435–4433.

Name of Committee: Oncological sciences Integrated Review Group, Chemical Pathology Study Section.

Date: June 16–18, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Victor A. Fung, PhD, Scientific Review Administrator, Oncological Sciences Initial Review Group, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6178, MSC 7804, Bethesda, MD 20814–9692, 301–435–3504, *vf6@nih.gov.*

Name of Committee: Endocrinology and Reproductive Sciences Integrated Review Group, Endocrinology Study Section.

Date: June 16–17, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Syed M. Amir, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6168, MSC 7892, Bethesda, MD 20892, (301) 435–1043, *amirs@csr.nih.gov.*

Name of Committee: Musculoskeletal and Dental Sciences Integrated Review Group, General Medicine B Study Section.

Date: June 16–17, 2003.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Shirley Hilden, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, MSC 7814, Bethesda, MD 20892, (301) 435–1198.

Name of Committee: Cardiovascular Sciences Integrated Review Group, Experimental Cardiovascular Sciences Study Section.

Date: June 16–17, 2003.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person: Anshumali Chaudhari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210.

Name of Committee: Endocrinology and Reproductive Sciences Integrated Review Group, Reproductive Endocrinology Study Section.

Date: June 16–17, 2003.

Time: 8:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Abubakar A. Shaikh, DVM, PhD, Scientific Review Administrator, ENR IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6168, MSC 7892, Bethesda, MD 20892–9692, (301) 435–1042, *shaikha@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 IFCN–2 (01) Neuroendocrinology, Neuroimmunology, and Behavior.

Date: June 16–17, 2003.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Richard Marcus, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5168, MSC 7844, Bethesda, MD 20892, 301–435–1245, *richard.marcus@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fogarty International Collaboration Program.

Date: June 17–18, 2003.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Ping Fan, MD, PhD, Scientific Review Administrator, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm. 5154, MSC 7840, Bethesda, MD 20892, 301–435–1740, *fanp@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Integrative, Functional and Cognitive Neuroscience 4.

Date: June 17–18, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: Dan Kenshalo, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 5176, MSC 7844, Bethesda, MD 20892, 301–435–1255.

Name of Committee: Center for Scientific Review Special Emphasis Panel Biosensors.

Date: June 17, 2003.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Pooks Hill Marriot, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: John L. Bowers, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435–1725.

Name of Committee: Pathophysiological Sciences Integrated Review Group, Respiratory Physiology Study Section.

Date: June 17–18, 2003.

Time: 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Everett E. Sinnett, PhD, Scientific Review Administrator, PPS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, (301) 435–1016, *sinnett@nih.gov.*

Name of Committee: Genetic Sciences Integrated Review Group, Mammalian Genetics Study Section.

Date: June 17–18, 2003.

Time: 9 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Cheryl M. Corsaro, PhD, Genetic Sciences IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892–7890, (301) 435–1045, *corsaroc@csr.nih.gov.*

Name of Committee: Biophysical and Chemical Sciences Integrated Review Group, Medicinal Chemistry Study Section.

Date: June 18–19, 2003.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Robert Lees, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4182, MSC 7806, Bethesda, MD 20892, (301) 435–2684, *leesro@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cell Development and Function R15 Applications.

Date: June 18, 2003.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Governor's House Hotel, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Alexandra M. Ainsztein, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5144, MSC 7840, Bethesda, MD 20892, (301) 451–3848, *ainsztea@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cell Death and Injury In Neurodegeneration Study Section.

Date: June 18–20, 2003.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Jefferson Hotel, 1200 16th Street, NW., Washington, DC 20036.

Contact Person: David L. Simpson, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5192, MSC 7846, Bethesda, MD 20892, (301) 435–1278, *simpsod@mail.nih.gov.*

Name of Committee: Genetic Sciences Integrated Review Group, Genome Study Section.

Date: June 18–20, 2003.

Time: 7:30 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sally Ann Amero, PhD, Scientific Review Administrator, Center for Scientific Review, Genetic Sciences Integrated Review Group, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892–7890, (301) 435–1159, *ameros@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13356 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Biobehavioral and Behavioral Processes 1, June 11, 2003, 9 a.m. to June 13, 2003, 5 p.m., Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC, 20037 which was published in the **Federal Register** on May 7, 2003, 68 FR 24493–24495.

The meeting time has been changed to 8 a.m. on June 11, 2003, 8 p.m. on June 13, 2003. The meeting dates and location remain the same. The meeting is closed to the public.

Dated: May 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13358 Filed 5–28–03; 8:45 am]

BILLING CODE 4140–01–M

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 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 (301) 443–7978.

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: Survey of SAMHSA Grantees Involved with Coordination of HIV, Substance Abuse, Mental Health and Hepatitis Programs—New—SAMHSA's Office of the Administrator/Office of Policy Planning and Budget plans to request assistance in the development of criteria to evaluate best practices to coordinate HIV, substance abuse, mental health, and hepatitis programs through a survey of SAMHSA grantees involved with coordination of HIV, substance abuse, mental health, and hepatitis programs. These are grantees funded by the Centers for Substance Abuse Treatment and the Centers for Substance Abuse Prevention under programs which fund the coordination of services across one or more of the following areas: Substance abuse prevention or treatment, mental health, HIV, and hepatitis.

To date, there is a lack of consensus among federal agencies, state agencies, and local providers regarding what integration of services means, what it entails, and what constitutes a ''best practice.'' By 2004, SAMHSA will develop grant programs to evaluate the coordination of programs and services across substance abuse, mental health, HIV, and hepatitis. The inclusion of grantee opinions regarding criteria for the evaluation of coordination, current practices to evaluate coordination, and barriers which impede grantee evaluation of service coordination will be of tremendous value to SAMHSA as the agency develops the requirements for funding and future technical assistance programs. SAMHSA grantees are currently implementing programs to coordinate services and can provide invaluable advice to SAMHSA so that the evaluation of coordination is relevant for the improvement of future programs and services.

To gather grantee feedback, SAMHSA will conduct a one-time survey of grantees. Information will be gathered using a 16 question instrument developed to gather both quantitative and qualitative information. The survey will be distributed by email containing the web link to a website that will assure grantee confidentiality and reduce respondent or administrative burden related to responding to the survey. Grantees will be able to return the survey via email, fax, or mail. Grantees will be assured in writing that their survey responses will not be linked to their grantee organization. The following table summarizes the response burden for this survey.

Number of respondents	Responses per respondent	Burden per response (in hours)	Total burden hours
248	1	.75	105

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 21, 2003.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 03–13380 Filed 5–28–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2003 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability for SAMHSA Services Grant Program for Residential Treatment for Pregnant and Postpartum Women.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) announces the availability of FY 2003 funds for the grant program described below. A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, is also available at the Internet site: *http://www.fedgrants.gov.*

This notice is not a complete description of the program; potential applicants must obtain a copy of the Request for Applications (RFA), including Part I, Services Grant Program for Residential Treatment for Pregnant and Postpartum Women, Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application.

Funding Opportunity Title: Services Grant Program for Residential Treatment for Pregnant and Postpartum Women—Short Title: PPW.

Funding Opportunity Number: TI 03–012.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section: 508 of the Public Health Service Act, as amended and subject to the availability of funds.

Funding Opportunity Description: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) is accepting applications for Fiscal Year 2003 grants to expand the availability of comprehensive, high quality residential treatment services for pregnant and postpartum women (postpartum refers to the period after childbirth—up to 12 months) who suffer from alcohol and other drug use problems, and for their infants and children impacted by the perinatal and environmental effects of maternal substance use and abuse.

Eligible Applicants: Domestic public and non-profit private entities, including tribal governments/organizations, community- and faith-based organizations, may apply.

Due Date for Applications: July 23, 2003.

Estimated Funding Available/Number of Awards: It is expected that approximately $3 million will be available for 6 to 9 awards in FY 2003. The average annual award will range from $350,000 to $500,000 in total costs (direct and indirect). Actual funding levels will depend on the availability of funds. Applications with proposed budgets that exceed $500,000 will be returned without review.

Is Cost Sharing Required: Yes. Non-Federal contributions are required and may be in cash or in-kind, fairly evaluated. The matching funds must not be less than $1 for each $9 of Federal funds provided in years one and two, and not less than $1 for each $3 of Federal funds in any subsequent year. Matching funds must meet the same test of allowability as costs charged to Federal grants. Sources of matching funds are State and local governmental appropriations (non-Federal), foundations, and other private non-profit or for-profit organizations. In-kind contributions may include facilities, equipment, or services used in direct support of the project.

Period of Support: Up to 3 years, with annual continuations depending on availability of funds and progress achieved.

How to Get Full Announcement and Application Materials: Complete application kits may be obtained from: the National Clearinghouse for Alcohol and Drug Information (NCADI) at 1–800–729–6686. The PHS 5161–1 application form and the full text of the funding announcement are also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov* (Click on 'Grant Opportunities').

When requesting an application kit, the applicant must specify the funding opportunity title and number for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

Contact for Additional Information: Linda White Young, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, 5600 Fishers Lane/Rockwall II, 7th Floor, Rockville, MD 20857, (301) 443–8392, E-Mail: *Lwhite1@samsha.gov.*

Dated: May 20, 2003.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–13393 Filed 5–28–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species and/or marine mammals.

DATES: Written data, comments or requests must be received by June 30, 2003.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents

within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION:

Endangered Species

The public is invited to comment on the following application(s) for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

PRT–071236

Applicant: James B. Rolls, Fenton, MI.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

PRT–071239

Applicant: Adam Andreini, San Mateo, CA.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

PRT–075509

Applicant: Scott C. Klemp, El Dorado Hill, CA.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Endangered Marine Mammals and Marine Mammals

The public is invited to comment on the following application(s) for a permit to conduct certain activities with endangered marine mammals and/or marine mammals. The application(s) was/were submitted to satisfy requirements of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*) and/or the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), and the regulations governing endangered species (50 CFR part 17) and/or marine mammals (50 CFR part 18). Written data, comments, or requests for copies of the complete applications or requests for a public hearing on these applications should be submitted to the Director (address above). Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

PRT–071227

Applicant: Robert W. Ehle, Orefield, PA.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport hunted from the Northern Beaufort Sea polar bear population in Canada for personal use.

The U.S. Fish and Wildlife Service has information collection approval from OMB through March 31, 2004, OMB Control Number 1018–0093. Federal Agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number.

Dated: May 2, 2003.

Charles S. Hamilton,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. 03–13288 Filed 5–28–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits for endangered species.

SUMMARY: The following permits were issued.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on the dates below, as authorized by the provisions of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*), the Fish and Wildlife Service issued the requested permit(s) subject to certain conditions set forth therein. For each permit for an endangered species, the Service found that (1) the application was filed in good faith, (2) the granted permit would not operate to the disadvantage of the endangered species, and (3) the granted permit would be consistent with the purposes and policy set forth in section 2 of the Endangered Species Act of 1973, as amended.

Endangered Species

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
054484	Tarzan Zerbini Circus	68 FR 15478; March 31, 2003	May 1, 2003.
065144	Tarzan Zerbini Circus	68 FR 15478; March 31, 2003	May 1, 2003.
065145	Tarzan Zerbini Circus	68 FR 15478; March 31, 2003	May 1, 2003.
065146	Tarzan Zerbini Circus	68 FR 15478; March 31, 2003	May 1, 2003.
065147	Tarzan Zerbini Circus	68 FR 15478; March 31, 2003	May 1, 2003.
065148	Tarzan Zerbini Circus	68 FR 15478; March 31, 2003	May 1, 2003.
065149	Tarzan Zerbini Circus	68 FR 15478; March 31, 2003	May 1, 2003.
068868	Thomas U. Dudley	68 FR 15477; March 31, 2003	May 5, 2003.

Dated: May 9, 2003.

Charles S. Hamilton,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. 03–13289 Filed 5–28–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications.

SUMMARY: The following applicants have applied for a scientific research permit to conduct certain activities with endangered species pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended.

DATES: To ensure consideration, written comments must be received on or before June 30, 2003.

ADDRESSES: Written comments should be submitted to the Chief, Endangered Species Division, Ecological Services, P.O. Box 1306, Albuquerque, New Mexico 87103. Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act. Documents will be available for public inspection, by appointment only, during normal business hours at the U.S. Fish and Wildlife Service, 500 Gold Avenue SW., Room 4102, Albuquerque, New Mexico. Please refer to the respective permit number for each application when submitting comments. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public.

FOR FURTHER INFORMATION CONTACT: Chief, Endangered Species Division, (505) 248–6920.

SUPPLEMENTARY INFORMATION:

Permit No. TE–069360

Applicant: Robert Forrest, Mesa, Arizona

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys for the following species within Arizona: southwestern willow flycatcher (*Empidonax traillii extimus*), cactus ferruginous pygmy owl (*Glaucidium brasilianum cactorum*), Yuma clapper rail (*Rallus longirostris yumanensis*), northern aplomado falcon (*Falco femoralis septentrionalis*), California condor (*Gymnogyps californianus*), Sonoran pronghorn (*Antilocapra americana sonoriensis*), humpback chub (*Gila cypha*), Virgin River chub (*Gila robusta semidnuda*), Yaqui chub (*Gila purpurea*), Colorado pikeminnow (*Ptychocheilus lucius*), desert pupfish (*Cyprinodon macularius*), razorback sucker (*Xyrauchen texanus*), Gila (incl. Yaqui) topminnow (*Poeciliopsis occidentalis*), Gila trout (*Oncorhynchus gilae*), and woundfin (*Plagopterus argentissimus*).

Permit No. TE–833868

Applicant: URS Corporation, Tucson, Arizona

Applicant requests an amendment to an existing permit to allow presence/absence surveys for the following species within Arizona: Colorado pikeminnow (*Ptychocheilus lucius*), desert pupfish (*Cyprinodon macularius*), and Gila (incl. Yaqui) topminnow (*Poeciliopsis occidentalis*).

Permit No. TE–045236

Applicant: SWCA Environmental, Inc., Phoenix, Arizona

Applicant requests an amendment to an existing permit to allow presence/absence surveys for northern aplomado falcon (*Falco femoralis septentrionalis*) within New Mexico.

Permit No. TE–041868

Applicant: Kevin Hamann, Tijeras, New Mexico.

Applicant request an amendment to an existing permit to allow presence/absence surveys for cactus ferruginous pygmy owl (*Glaucidium brasilianum cactorum*) within Arizona.

Permit No. TE–069320

Applicant: KBA EnviroScience, Inc., Lewisville, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys and baiting out activities for the American burying beetle (*Nicrophorus americanus*) within Oklahoma.

Permit No. TE–799099

Applicant: Eagle Ecological Services, Inc., Santa Fe, New Mexico.

Applicant requests an amendment to an existing permit to allow presence/absence surveys for least tern (*Sterna antillarum*) within New Mexico and Texas.

Permit No. TE–020844

Applicant: Engineering and Environmental Consultants, Inc., Tucson, Arizona.

Applicant requests an amendment to an existing permit to allow presence/absence surveys for Yuma clapper rail (*Rallus longirostris yumanensis*) within Arizona.

Permit No. TE–069849

Applicant: Phase One Technologies, LLC, Houston, Texas.

Applicant requests a new permit for research and recovery purposes to allow presence/absence surveys for the following species within Texas: red-cockaded woodpecker (*Picoides borealis*), Attwater's greater prairie-chicken (*Tympanuchus cupido attwateri*), whooping crane (*Grus americana*), brown pelican (*Pelecanus occidentalis*), piping plover (*Charadrius melodus*), Eskimo curlew (*Numenius borealis*), and least tern (*Sterna antillarum*).

Permit No. TE–069848

Applicant: Ross Rasmussen, Plano, Texas.

Applicant requests a new permit for research and recovery purposes to allow presence/absence surveys for golden-cheeked warbler (*Dendroica chrysoparia*) and black-capped vireo (*Vireo atricapillus*) within Texas; northern aplomado falcon (*Falco femoralis septentrionalis*) within Arizona, New Mexico, and Texas; and southwestern willow flycatcher (*Empidonax traillii extimus*) within Arizona, New Mexico, Texas, and California.

Permit No. TE–069847

Applicant: Muukui-ci Cultural and Environmental Services, LLC., Aztec, New Mexico.

Applicant requests a new permit for research and recovery purposes to allow presence/absence surveys for southwestern willow flycatcher (*Empidonax traillii extimus*) within Arizona, New Mexico, Utah, and Colorado.

Permit No. TE–038608

Applicant: USGS, Biological Research Division, Sonoran Desert Field Station, Tucson, Arizona.

Applicant requests an amendment to an existing permit to allow presence/absence surveys for razorback sucker (*Xyrauchen texanus*) within Arizona.

Permit No. TE–068896

Applicant: Cynthia Baker, Austin, Texas.

Applicant requests a new permit for research and recovery purposes to allow presence/absence surveys and nest monitoring for golden-cheeked warbler (*Dendroica chrysoparia*) and black-capped vireo (*Vireo atricapillus*) within Texas.

Permit No. TE–022190

Applicant: Arizona-Sonora Desert Museum, Tucson, Arizona.

Applicant requests an amendment to an exiting permit to allow presence/absence surveys for cactus ferruginous pygmy owl (*Glaucidium brasilianum cactorum*) within Arizona.

Authority: 16 U.S.C. 1531, *et seq.*

Dated: May 6, 2003.

Susan MacMullin,

Acting Assistant Regional Director, Ecological Services, Region 2, Albuquerque, New Mexico.

[FR Doc. 03–13381 Filed 5–28–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Application of Endangered Species Recovery Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We announce our receipt of an application to conduct certain activities pertaining to scientific research and enhancement of survival of endangered species.

DATES: Written comments on this request for a permit must be received June 30, 2003.

ADDRESSES: Written data or comments should be submitted to the Assistant Regional Director-Ecological Services, U.S. Fish and Wildlife Service, PO Box 25486, Denver Federal Center, Denver, Colorado 80225–0486; telephone 303–236–7400, facsimile 303–236–0027.

FOR FURTHER INFORMATION CONTACT: Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 20 days of the date of publication of this notice to the address above; telephone 303–236–7400.

SUPPLEMENTARY INFORMATION: The following applicant has requested issuance of a scientific research and enhancement of survival permit to conduct certain activities with endangered species pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

TE–070027

Applicant: Renae Held, Tern and Plover Conservation Partnership, University of Nebraska, Lincoln, Nebraska.

The applicant requests a permit to take Interior least terns (*Sterna antillarum athalassos*) and piping plovers (*Charadrius melodus*) in conjunction with recovery activities throughout the species' ranges for the purpose of enhancing their survival and recovery.

TE–071662

Applicant: Fred Lindzey, Laramie, Wyoming.

The applicant requests a permit to take Wyoming toads (*Bufo baxteri*) in conjunction with recovery activities throughout the species' range for the purposes of enhancing their survival and recovery.

Dated: April 22, 2003.

John A. Blankenship,

Regional Director, Denver, Colorado.

[FR Doc. 03–13382 Filed 5–28–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Application for Endangered Species Permit: Permits for Scientific Purposes, Enhancement of Propagation or Survival i.e., Recovery Permits), and Interstate Commerce Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application for endangered species permit.

SUMMARY: The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

DATES: Written data or comments on these applications must be received, at the address given below, by June 30, 2003.

ADDRESSES: Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act,* by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Victoria Davis, Permit Biologist). Telephone: 404/679–4176; Facsimile: 404/679–7081.

FOR FURTHER INFORMATION CONTACT: Victoria Davis, Telephone: 404/679–4176; Facsimile: 404/679–7081.

SUPPLEMENTARY INFORMATION: If you wish to comment, you may submit comments by any one of several methods. You may mail comments to the Service's Regional Office (*see* **ADDRESS**). You may also comment via the internet to ''*victoria_davis@fws.gov.*'' Please submit comments over the internet as an ASCII file avoiding the use of special characters and any form of encryption. Please also include your name and return address in your internet message. If you do not receive a confirmation from the Service that we have received your internet message, contact us directly at either telephone number listed above (*see* **FURTHER INFORMATION**). Finally, you may hand deliver comments to the Service office listed below (*see* **ADDRESS**). Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the administrative record. We will honor such requests to the extent allowable by law. There may also be other circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and address, you must state this prominently at the beginning of your comments. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

TE067738–0

Applicant: Lowry Park Zoo, Jennifer Elizabeth Hackshaw, Tampa, Florida.

The applicant requests authorization to receive up to twelve injured and disabled Key Deer (*Odocoileus virginianus clavium*) for veterinary treatment and rehabilitation. The Key Deer will be identified by personnel at and transferred from the Key Deer National Wildlife Refuge, Monroe County, Florida. They will be housed at the Lowery Park Zoo, Hillsborough County, Florida.

Applicant: J.W. Jones Ecological Research Center, Ichauway, Inc., Newton, Georgia, TE066980–0.

The applicant requests authorization to take (capture, band, release, monitor nests, and install and drill artificial cavity inserts) red-cockaded woodpeckers (*Picoides borealis*) while conducting presence and absence surveys and management activities. The proposed activities will take place at the Joseph W. Jones Ecological Research Center, Ichauway, Baker County, Georgia.

TE069236–0

Applicant: U.S. Geological Survey, Wiley M. Kitchens, Gainesville, Florida

The applicant requests authorization to take (survey, capture, band, radio-tag, release, recapture, exam and measure, take feather samples, monitor nest) the snail kite (*Rostrhamus sociabilis*) while collecting information on the demography and movement of the species. The surveys will be performed throughout several wetlands in central and south Florida, including Lake Kissimmee, East and West Lake Tohopekaliga, Lake Okeechobee, Blue Cypress Marshes of the upper Saint Johns, West Palm Beach Water Catchment area (Grassy Water Preserve), ARM Loxahatchee National Wildlife Refuge, Water Conservation Areas 2A, 2B, 3A, and 3B, Big Cypress National Preserve, and the Everglades National Park, including Shark Valley and North East Shark River Slough, Florida.

TE069697–0

Applicant: University of Tennessee at Martin, Department of Agriculture and Natural Resources, 256 Brehm Hall, Martin, Tennessee

The applicant requests authorization to take (collect and display dead relic shells) for educational purposes for the following species: Southern acornshell (*Epioblasma othcaloogensis*), Cumberland (pearlymussel) bean (*Villosa trabalis*), purple bean (*Villosa perpurpurea*), green (pearlymussel) blossom (*Epioblasma torulosa gubernaculum*), tubercled (pearlymussel) blossom (*Epioblasma torulosa torulosa*), turgid (pearlymussel) blossom (*Epioblasma turgidula*), yellow (pearlymussel) blossom (*Epioblasma florentina florentina*), Catspaw (=purple cat's paw pearlymussel) (*Epioblasma obliquata obliquata*), Cumberlandian combshell (*Epioblasma brevidens*), upland combshell (*Epioblasma metastriata*), Appalachian elktoe (*Alasmidonta raveneliana*), Cumberland elktoe (*Alasmidonta atropurpurea*), fanshell (*Cyprogenia stegaria*), triangular kidneyshell (*Ptychobranchus greeni*), Alabama lampmussel (*Lampsilis virescens*), pale (pearlymussel) lilliput (*Toxolasma cylindrellus*), winged (mussel) mapleleaf (*Quadrula fragosa*), royal (snail) marstonia (*Pyrgulopsis ogmorhaphe*), Coosa moccasinshell (*Medionidus parvulus*), Appalachian (pearlymussel) monkeyface (*Quadrula sparsa*), Cumberland (pearlymussel) monkeyface (*Quadrula intermedia*), pink (pearlymussel) mucket (*Lampsilis abrupta*), oyster mussel (*Epioblasma capsaeformis*), birdwing pearlymussel (*Conradilla caelata*), cracking pearlymussel (*Hemistena lata*), dromedary pearlymussel (*Dromus dromas*), littlewing pearlymussel (*Pagias fabula*), Cumberland pigtoe (*Pleurobema gibberum*), finerayed pigtoe (*Fusconaia cuneolus*), rough pigtoe (*Pleurobema plenum*), shiny pigtoe (*Fusconaia cor* (=*edgariana)*), southern pigtoe (*Pleurobema georgianum*), orangefoot (pearlymussel) pimpleback (*Plethobasus cooperianus*), finelined pocketbook (*Lampsilis altilis*), rough rabbitsfoot (*Quadrula cylindrica strigillata*), tan riffleshell (*Epioblasma florentina walkeri* (=*E. Walkeri)*), ring (mussel) pink (*Obovaria retusa*), Anthony's riversnail (*Athearnia anthonyi*), painted snake coiled forest snail (*Anguispira picta*), and white (pearlymussel) wartyback (*Plethobasus cicatricosus*). The proposed activities will take place throughout the state of Tennessee.

TE069754–0

Applicant: Gerald R. Dinkins, Dinkins Biological Consulting, Powell, Tennessee

The applicant requests authorization to take (survey, capture, release, translocate, and collect relict shells) all federally listed freshwater fishes and mussels identified in 50 CFR 17.11.

The proposed take will occur while conducting contract work with the Georgia Department of Transportation, Tennessee Department of Transportation, and other clients across the states of Georgia, Tennessee, and Alabama.

TE070584–0

Applicant: Mark W. Gumbert, Richmond, Kentucky.

The applicant requests authorization to take (survey, monitor, capture, band, radio tag, take tissue samples, release, track, and collect fecal samples) the following species: gray bat (*Myotis grisescens*), Indiana bat (*Myotis sodalis*), Ozark big-eared bat (*Corynorhinus townsendii ingens*), and the Virginia big-eared bat (*Corynohinus* (=*Plecoyus*) *townsendii virginianus*). Take may occur while conducting presence/absence surveys and during monitoring of the populations. The proposed activities will take place in Iowa, Missouri, Arkansas, Illinois, Indiana, Mississippi, Wisconsin, Ohio, Alabama, Georgia, North Carolina, South Carolina, West Virginia, Massachusetts, Vermont, New Hampshire, Rhode Island, Oklahoma, Virginia, Tennessee, Kansas, and Kentucky.

TE070796–0

Applicant: Apogee Environmental Consultants, Joel Beverly, Whitesburg, Kentucky.

The applicant requests authorization to take (survey, monitor, capture, band, radio tag, photograph, release, and track) the following species: gray bat (*Myotis grisescens*), Indiana bat (*Myotis sodalis*), and the Virginia big-eared bat (*Corynohinus* (=*Plecoyus*) *townsendii virginianus*). Take may occur while conducting presence/absence surveys and during monitoring of the populations. The proposed activities will take place in Iowa, Missouri, Arkansas, Illinois, Indiana, Mississippi, Wisconsin, Ohio, Alabama, Georgia, North Carolina, South Carolina, West Virginia, Massachusetts, Vermont, New Hampshire, Rhode Island, Oklahoma, Virginia, Tennessee, Kansas, Maryland, Michigan, New Jersey, New York, Pennsylvania, and Kentucky.

TE070800–0

Applicant: Ecological Solutions, Inc., John Erik Alford, Roswell, Georgia.

The applicant requests authorization to take (survey, capture, release, and retain 5 individuals of each species of invertebrates and darters) the following species: blue shiner (*Cyprinella caerulea*), Etowah darter (*Etheostoma etowahae*), Cherokee darter (*Etheostoma scotti*), Amber darter (*Percina antesella*), goldline darter (*Percina aurolineata*), Conasauga logperch (*Percina jenkinsi*), snail darter (*Percina tanasi*), fat threeridge (*Amblema neislerii*), purple bankclimber (*Elliptoideus sloatianus*), upland combshell (*Epioblasma metastriata*), southern acornshell (*Epioblasma othcaloogensis*), southern combshell (*Epioblasma penita*), fine-lined pocketbook (*Lampsilis altilis*), orange-nacre mucket (*Lampsilis perovalis*), shinyrayed pocketbook (*Lampsilis subangulata*), Alabama moccasinshell (*Medionidus acutissimus*), Coosa moccasinshell (*Medionidus parvulus*), gulf moccasinshell (*Medionidus penicillatus*), Ochlockonee moccasinshell (*Medionidus simpsonianus*), southern clubshell (*Pleurobema decisum*), southern pigtoe

(*Pleurobema georgianum*), ovate clubshell (*Pleurobema perovatum*), oval pigtoe (*Pleurobema pyriforme*), triangular kidneyshell (*Ptychobranchus greenii*), eastern indigo snake (*Drymarchon couperi*), and gopher tortoise (*Gopherus polyphemus*), and while conducting presence and absence studies. The collection of invertebrates and darters are limited to cases where they are unable to be identified in the field. When invertebrates and darters are collected, they will be preserved and donated to an accredited Natural History Museum or educational institution. The applicant also requests authorization to disturb the following species while conducting presence and absence surveys on Federal property: *Amphianthus pusillus* (little amphianthus), *Baptisia arachnifera* (hairy rattleweed), *Clematis socialis* (Alabama leather flower), *Echinacea laevigata* (smooth purple coneflower), *Gymnoderma lineare* (Rock Gnome lichen), *Helonia bullata* (swamp-pink), *Isoetes melanospora* (black-spored quillwort), *Isoetes tegetiformans* (mat-forming quillwort), *Isotria medeoloides* (small whorled pogonia), *Lindera melissifolia* (pondberry), *Marshallia mohrii* (Coosa Barbara buttons), *Oxypolis canbyi* (Canby dropwort), *Ptilimnium nodosum* (harperella), *Rhus michauxii* (dwarf sumac), *Sagittari secundifolia* (Little River Water-plantain), *Sarracenia oreophila* (green pitcherplant), *Schwalbea americana* (chaffseed), *Silene polypetala* (fringed campion), *Spiraea virginiana* (Virginia spirea), *Thalictrum cooleyi* (Cooley medowrue), *Torreya taxifolia* (Florida torreya), *Trillium persistens* (persistent trillium), *Trillium reliquum* (relict trillium), and *Xyris tennesseensis* (Tennessee yellow-eyed grass). The proposed activities will take place in the state of Georgia.

TE070810–0

Applicant: Terracon, Inc., Jamal Najm, Duluth, Georgia.

The applicant requests authorization to take (survey, capture, identify, and release) the following species: fat three-ridge (*Amblema neislerii*), Chipola slabshell (*Elliptio chipolaensis*), purple bankclimber (*Elliptoideus sloatianus*), upland combshell (*Epioblasma metastriata*), southern acornshell (*Epioblasma othcaloogensis*), fine-lined pocketbook (*Lampsilis altilis*), shiny-rayed pocketbook (*Lampsilis subangulata*), Alabama moccasinshell (*Medionidus acutissimus*), Coosa moccasinshell (*Medionidus parvulus*), gulf moccasinshell (*Medionidus penicillatus*), Ochlockonee moccasinshell (*Medionidus simpsonianus*), southern clubshell (*Pleurobema decisum*), southern pigtoe (*Pleurobema georgianum*), ovate clubshell (*Pleurobema perovatum*), triangular kidneyshell (*Ptychobranchus greeni*), oval pigtoe (*Pleurobema pyriforme*), shortnose sturgeon (*Acipenser brevirostrum*), blue shiner (*Cyprinella caerulea*), Cherokee darter (*Etheostoma scotti*), Etowah darter (*Etheostoma etowahae*), amber darter (*Percina antesella*), goldline darter (*Percina aurolineata*), Conasauga logperch (*Percina jenkinsi*), and snail darter (*Percina tanasi*). The purpose of the take is to determine presence or absence and potential impacts to the species due to road and bridge projects. The proposed activities will occur throughout the state of Georgia.

TE070846–0

Applicant: Jeffery Ray Walters, Virginia Tech, Blacksburg, Virginia.

The applicant requests authorization to take (capture, band, radio-tag, release, track, translocate, blood sampling, monitor nests, and construct and install artificial cavity inserts) red-cockaded woodpeckers (*Picoides borealis*) while conducting presence and absence surveys, population monitoring, and various research studies. The take activities will occur in North Carolina, South Carolina, and Florida.

TE068217–0

Applicant: Alabama A&M University, William E. Stone, Normal, Alabama.

The applicant requests authorization to take (survey, capture, mark, band, radio-tag, track, recapture, and release) the gray bat (*Myotis grisescens*) and Indiana bat (*Myotis sodalis*) to collect information on summer habitat requirements for roosting, foraging, and home range used by the species and other rare bats. The information acquired will be used to evaluate the adequacy of current protection measures. The proposed activities will occur on the Bankhead National Forest, Alabama.

TE068229–0

Applicant: Martin County Parks and Recreation, Robert F. Denison, Stuart, Florida.

The applicant requests authorization to take wood storks (*Mycteria americana*) by harassment that will occur while conducting aerial and boat surveys and ground observations during the nesting season; while removing and chemically treating nuisance exotic plant species; and while planting native vegetation. Harassment may take place while conducting restoration and enhancement activities on dredged material on Bird Island located in the Indian River Lagoon, Martin County, Florida.

Dated: May 13, 2003.

Linda H. Kelsey,

Acting Regional Director.

[FR Doc. 03–13383 Filed 5–28–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permit for marine mammals.

SUMMARY: The following permit was issued.

ADDRESSES: Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on the dates below, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service issued the requested permit(s) subject to certain conditions set forth therein.

Per No.	Applicant	Receipt of application *Federal Register* notice	Permit issuance date
067553	Daniel Kehoe	68 FR 10026; March 3, 2003	April 23, 2003

Dated: May 2, 2003.

Charles S. Hamilton,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. 03–13287 Filed 5–28–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

National Park Service

30-Day Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of submission to OMB and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13), this notice announces the National Park Service's (NPS) intention to request an extension for a currently approved information collection request (OMB control number 1024–009) used in the Historic Preservation Tax Incentives Program administered by the NPS.

The Primary Purpose of the Information Collection Request: Section 47 of the Internal Revenue Code requires that the Secretary of the Interior certify to the Secretary of the Treasury upon application by owners of historic properties for Federal tax benefits, (a) the historic character of the property, and (b) that the rehabilitation work is consistent with that historic character. The NPS administers the program in partnership with the Internal Revenue Service. The Historic Preservation Certification Application is used by the NPS to evaluate the condition and historic significance of buildings undergoing rehabilitation for continued use, and to evaluate whether the rehabilitation work meets the Secretary of the Interior's ''Standards for Rehabilitation.''

DATES: Comments on this notice must be received by June 30, 2003 to be assured of consideration.

ADDRESSES: Send comments to: Attention: Desk Officer for the Department of the Interior, OMB Office of Information and Regulatory Affairs, via facsimile at (202) 395–5806, or via e-mail at *Ruth_ Solomon@omb.eop.gov.* Also send a copy of your comments to: Sharon C. Park, Heritage Preservation Services, National Park Service, 1949 C St., NW., Org. code 2255, Washington, D.C. 20240–0001.

FOR FURTHER INFORMATION CONTACT: Michael Auer, 202–354–2031.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 and 5 CFR part 1320, Reporting and Record Keeping Requirements, the bureau solicits public comments on the Historic Preservation Certification Application as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the bureau, including whether the information will have practical utility;
2. The accuracy of the bureau's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
3. The quality, utility, and clarity of the information to be collected; and,
4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology.
5. The appropriateness of the filing fee. In addition to the hour burden, there is a filing fee for applications describing rehabilitation projects over $20,000. The fee is based on the size of the rehabilitation, according to a fee schedule published in 36 CFR 67.11, as follows:

Fee	Size of rehabilitation
$500	$20,001 to $99,999
$800	$100,000 to $499,999
$1,500	$500,000 to $999,999
$2,500	$1,000,000 or more

Historic Preservation Certification application (36 CFR Part 67.3)

1. *Title:* Historic Preservation Certification Application.
2. *Summary:* Request for an extension for a currently approved information collection request (OMB control number 1024–009) used in the Historic Preservation Tax Incentives Program administered by the NPS.
3. *Need for information and proposed use:* To enable the Secretary of the Interior to make certifications to the Secretary of the Treasury concerning historic buildings undergoing rehabilitation for the purposes of a Federal income tax credit.
4. Respondents are owners of historic buildings, or qualified long-term lessees. The number of respondents is estimated to be 3,000 per year. The frequency of response is on occasion, as requested by owners of buildings (one response per respondent).
5. The total annual reporting and recordkeeping burden is estimated to be 7,500 hours.
6. The non-hour dollar burden (based on filing fees) is estimated to be $1,000,000.

Dated: May 22, 2003.

Linda M. Newbold,

Acting, NPS Information Collection Clearance Officer.

[FR Doc. 03–13328 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–52–M

DEPARTMENT OF THE INTERIOR

National Park Service

Information Collection; Request for Extension

AGENCY: National Park Service, Interior.

ACTION: Notice of request for a currently approved information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 and 5 CFR part 1320, the National Park Service (NPS) is announcing its intention to request an extension for a currently approved information collection under 36 CFR part 51 relating to the submission of offers in response to concession prospectuses issued by NPS. This program will measure performance in meeting goals as required by the 1995 Government Performance and Results Act. Send comments on (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; (4) and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information.

DATES: Comments on this notice must be received no later than July 28, 2003.

Additional Information or Comments: Contact Cynthia Orlando, Concession Program Manager, National Park Service, 1849 C Street, NW., (2410), Washington, DC 20240, or 202/513–7144.

SUPPLEMENTARY INFORMATION:

Title: Submission of Offers in response to concession opportunities.

OMB Control Number: 1024–0125.

Expiration Date of Approval: August 31, 2003.

Type of Request: Extension of a currently approved information collection.

Abstract: The regulations at 36 CFR part 51 primarily implement Title IV of the National Parks Omnibus Management Act of 1998 (Pub. L. 105–391 or the Act), which provides new legislative authority, policies and requirements for the solicitation, award and administration of NPS concession contracts. The regulations require the

submission of offers by parties interested in applying for a NPS concession contract. Specific requirements regarding the information that must be submitted by offerors in response to a prospectus issued by NPS are contained in sections 403(4), (5), (7), and (8) of the Act.

Bureau Form Number: None.

Frequency of Collection: On occasion.

Description of Respondents: Persons or entities seeking a National Park Service concession contract.

Total Annual Responses: 240.

Estimate of Burden: Approximately 56 hours per response.

Total Annual Burden Hours: 76,800.

Total Non-hour Cost Burden: $1,120,000.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Copies of the information collection can be obtained from Cynthia L. Orlando, Concession Program Manager, National Park Service, Department of the Interior, 1849 C Street, NW., (2410), Washington, DC 20240.

Dated: April 15, 2003.

Richard G. Ring,

Associate Director, Administration, Business Practices and Workforce Development.

[FR Doc. 03–13329 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–53–M

DEPARTMENT OF THE INTERIOR

National Park Service

Extension for Expiring Concession Contracts

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Pursuant to the terms of existing concession permits, with the exception of construction on National Park Service lands, public notice is hereby given that the National Park Service intends to provide visitor services under the authority of a temporary concession contract with a term of up to two years from the date of permit expirations.

SUPPLEMENTARY INFORMATION: The permits listed below, for charter and tour vessels at Glacier Bay National Park and Preserve, expired on December 31, 2003 and have been extended to the maximum allowable under 36 CFR 51.23. Under the provisions of current concessions permits, with one exception, and pending the development and public solicitation of a prospectus for a new concession contract, the National Park Service authorizes continuation of visitor services under a temporary concession contract for a period of up to two years from the expiration of the current concession permit. The exception precludes construction on National Park Service lands, regardless of whether the current permit authorizes such activity. The temporary contract does not affect my rights with respect to selection for award of a new concession contract. These temporary contracts will allow the National Park Service to complete a Congressionally mandated Environmental Impact Statement related to vessel management at Glacier Bay National Park and Preserve, followed by issuing prospectuses leading to the competitive selection of concessioners for new long-term concession contracts covering these operations. The EIS is scheduled for completion in December 2003. Prospectuses for charter and tour vessel operators are scheduled to be released in the Spring of 2004, authorizing charter vessel operations in 2005 and tour vessel operations in 2006.

Con ID No.	Concessioner name
Charter Vessels	
CP–GLBA015–98	Chicago of Charters.
CP–GLBA016–98	Grand Pacific Charters.
CP–GLBA018–98	Glacier Guides, Inc.
CP–GLBA019–98	Marine Adventure Sailing Tours.
CP–GLBA025–98	Princeton Hall, Ltd.
CP–GLBA026–98	Lisianski Charters.
CP–GLBA027–98	Gustavus Marine Charters, Inc.
CP–GLBA028–98	Elfin Cove Sportfishing Lodge.
CP–GLBA030–98	Dolphin Charters.
CP–GLBA031–98	Glacier Bay Country Inn.
CP–GLBA032–98	Sea Wolf Adventures.
Tour Vessels	
CP–GLBA037–98	New World Ship Management Co.
CP–GLBA038–98	Lindbald Expeditions, Inc.
CP–GLBA039–98	Cruise West.
CP–GLBA041–98	Glacier Bay Park Concessions, Inc.
CP–GLBA044–98	Glacier Bay Adventures.

EFFECTIVE DATE: June 30, 2003.

FOR FURTHER INFORMATION CONTACT: Cynthia Orlando, Concession Program Manager, National Park Service, Washington, DC, 20240, Telephone 202/513–7156.

Dated: May 6, 2003.

Richard G. Ring,

Associate Director, Administration, Business Practices and Workforce Development.

[FR Doc. 03–13332 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–HX–M

DEPARTMENT OF THE INTERIOR

National Park Service

Extension for Expiring Concession Contracts

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Pursuant to 36 CFR 51.23, public notice is hereby given that the National Park Service proposes to extend the following expiring concession permits, all at Glacier Bay National Park and Preserve, for a period of up to one year, or until such time as new contracts are executed, whichever occurs sooner.

SUPPLEMENTARY INFORMATION: All of the listed concession permits, which authorize cruise ship entries into Glacier Bay National Park and Preserve, will expire by their terms on December 31, 2004. The National Park Service has determined that the proposed short-term extensions are necessary in order to avoid interruption of visitor services and has taken all reasonable and appropriate steps to consider alternatives to avoid such interruption. These extensions will allow the National Park Service to complete a Congressionally mandated Environmental Impact Statement related to vessel management at Glacier Bay National Park and Preserve, followed by issuing prospectuses leading to the competitive selection of concessioners for new long-term concession contracts covering these operations. The EIS is scheduled for completion in December 2003. A prospectus is scheduled to be released in the Spring of 2004, allowing for contract award 16 months in advance of when the ships would enter the park.

Conc ID No.	Concessioner name
CP–GLBA002–00	Holland America Line Inc.
CP–GLBA003–00	Princess Cruises, Inc.
CP–GLBA004–00	Princess Cruises, Inc.
CP–GLBA005–00	Holland America Line Inc.
CP–GLBA006–00	World Explorer Cruises.
CP–GLBA007–00	NCL Cruise Line Ltd.
CP–GLBA036–00	Crystal Cruises, Inc.
CP–GLBA040–00	Cruise West.
CP–GLBA046–00	Celebrity Cruises, Inc.
CP–GLBA050–00	Carnival Cruise Line.

EFFECTIVE DATE: June 30, 2003.

FOR FURTHER INFORMATION CONTACT: Cynthia Orlando, Concession Program Manager, National Park Service, Washington, DC 20040, Telephone 202/513–7156.

Dated: May 6, 2003.

Richard G. Ring,

Associate Director, Administration, Business Practices and Workforce Development.

[FR Doc. 03–13333 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–HX–M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Issue a Temporary Concession Contract for Food and Beverage, Lodging, and Merchandise Services at Oregon Caves National Monument

SUMMARY: Pursuant to the National Park Service Concessions Management Improvement Act of 1998, notice is hereby given that the National Park Service intends to issue a temporary concession contract authorizing continued operation of food and beverage, overnight lodging and merchandise services to the public within Oregon Caves National Monument. The temporary concession contract will be for a term of not more than 1 year. This short-term concession contract is necessary to avoid interruption of visitor services while the National Park Service completes the solicitation and selection of a concessioner for a new long-term concession contract. This short-term contract will be for a one-seasonal operating period ending October 31, 2003. This notice is pursuant to 36 CFR part 51, section 51.24(a).

SUPPLEMENTARY INFORMATION: The previous concession contract at Oregon Caves National Monument expired on October 31, 2002. The operation is seasonal and operates primarily from mid-May through mid-September and provides visitors with lodging, food and beverage and merchandise services. The prospectus for Oregon Caves National Monument long-term concession contract was issued in February 2003 and the solicitation period will not be concluded until May of 2003. The review of proposals and selection of a concessioner will not be completed for another several months. The short-term concession contract is necessary to avoid the interruption of visitor services for the summer operating season of 2003 while the National Park Service conducts its solicitation and the evaluation of offers for the award of a new long-term concession contract.

Information about this notice can be sought from: National Park Service, Chief, Concession Program Management Office, Pacific West Region, Attn: Mr. Tony Sisto, 1111 Jackson Street, Suite 700, Oakland, California 94607 or call 510/817–1366.

Dated: May 1, 2003.

Richard G. Ring,

Associate Director, Administration, Business Practices and Workforce Development.

[FR Doc. 03–13331 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–06–M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent To Prepare a General Management Plan and Environmental Impact Statement for Cumberland Gap National Historical Park (KY, TN, VA)

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969 (NEPA), the National Park Service (Service) will prepare an Environmental Impact Statement (EIS) on the General Management Plan for Cumberland Gap National Historical Park. The EIS will assess potential environmental impacts associated with various types and levels of visitor use and resources management within the National Historical Park. This General Management Plan/EIS is being prepared in response to the requirements of the National Parks and Recreation Act of 1978, Public Law 95–625, and in accord with Director's Order Number 2, the planning directive for NPS units.

The NPS will conduct public scoping meetings in the local area to receive input from interested parties on issues, concerns, and suggestions pertinent to the management of Cumberland Gap National Historical Park. Representatives of the NPS will be available to discuss issues, resource concerns, and the planning process at each of the public meetings. Suggestions and ideas for managing the cultural and natural resources and visitor experiences at the park are encouraged.

DATES: Locations, dates, and times of public scoping meetings will be published in local newspapers and may also be obtained by contacting the park Superintendent. This information will also be published on the General Management Plan web site for Cumberland Gap, *http://www.nps.gov/cuga.*

ADDRESSES: Scoping suggestions should be submitted to the following address to ensure adequate consideration by the NPS: Superintendent, Cumberland Gap National Historical Park, P.O. Box 1848, Middlesboro, Kentucky 40965, Telephone: 606–248–2817, Email: *CUGA_Superintendent@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Superintendent, Cumberland Gap National Historical Park, P.O. Box 1848, Middlesboro, Kentucky 40965, Telephone: 606–248–2817, Email: *CUGA_Superintendent@nps.gov.*

SUPPLEMENTARY INFORMATION: Cumberland Gap National Historical Park is located on the tri-state boundaries of Kentucky, Virginia, and Tennessee. The park was authorized on June 11, 1940, and now consists of over 20,000 acres. The park lies in four counties in the three states, ranges from 1 to 4 miles in width, and stretches for 20 miles astride the forested Cumberland Mountain. Fourteen thousand acres in the park are managed as wilderness. The Cumberland Gap itself is a natural notch in the mountain ridge. It was this low passageway that provided access for travel among American Indian tribes and access for Daniel Boone and hundreds of thousands of settlers who poured into the west in the late 18th and early 19th centuries.

The Gap continued to serve as a strategic transportation corridor during the Civil War and during the late 19th-century period of intense industrial development. Today the Cumberland Gap Tunnel provides easy and safe vehicular travel among the connecting states, and the historic corridor has been returned to its natural topography. Visitors are able to walk in the footsteps of pioneers along the Wilderness Road through the restored Gap.

Public documents associated with the planning effort, including all newsletters, will be posted on the Internet through the park's website at *http://www.nps.gov/cuga.*

The Draft and Final General Management Plan/EIS will be made available to all known interested parties and appropriate agencies. Full public participation by Federal, State, and local agencies as well as other concerned organizations and private citizens is invited throughout the preparation process of this document. Please note that due to public disclosure requirements, the NPS, if requested, will make the names and addresses of those who submit written comments public. Anonymous comments will not be considered; however, individual respondents may request that we withhold their names and addresses from the public record. If you wish to withhold your name and/or address, you must state that request prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as

representatives or officials of organizations or businesses, available for public inspection in their entirety.

The responsible official for this Environmental Impact Statement is William W. Schenk, Regional Director, Southeast Region, National Park Service, 100 Alabama Street SW., 1924 Building, Atlanta, Georgia 30303.

Dated: April 18, 2003.

Charlie Powell,

Acting Regional Director, Southeast Region.

[FR Doc. 03–13334 Filed 5–28–03; 8:45 am]

BILLING CODE 4310–26–P

DEPARTMENT OF THE INTERIOR

National Park Service

General Management Plan/ Environmental Impact Statement, Montezuma Castle National Monument and Tuzigoot National Monument, Arizona

AGENCY: National Park Service, Interior.

ACTION: Notice of Intent to prepare an environmental impact statement for the general management plan, Montezuma Castle National Monument and Tuzigoot National Monument, Arizona.

SUMMARY: Under the provisions of the National Environmental Policy Act, the National Park Service is preparing an environmental impact statement for the general management plan for Montezuma Castle National Monument and Tuzigoot National Monument, Arizona. The environmental impact statement will be approved by the Director, Intermountain Region.

Montezuma Castle National Monument and Tuzigoot National Monument are located in Yavapai County, Arizona. Montezuma Castle was established in 1906 under the authority of the Antiquities Act. The proclamation states it ''* * * is of the greatest ethnological value and scientific interest * * *'' (Presidential Proclamation No. 696, December 8, 1906, 34 Stat. 3265). Montezuma Well was added in 1943 as a detached unit of the monument with an act of Congress (October 19, 1943, 57 Stat. 572).

Tuzigoot National Monument was established by presidential proclamation on July 25, 1939. The proclamation states that ''certain Government-owned lands in the State of Arizona have situated there on historic and prehistoric structures and other historic objects of historic or scientific interest, and * * * it would be in the public interest to reserve such lands as a national monument to be known as Tuzigoot National Monument.'' Public Law 95–625 (March 1978) expanded the boundary by approximately 791 acres.

The general management plan will prescribe the resource conditions and visitor experiences to be achieved and maintained in the monuments over the next 15 to 20 years. The clarification of what must be achieved according to law and policy will be based on review of the monuments' purpose, significance, special mandates, and the body of laws and policies directing management of the monuments. Management decisions to be made where law, policy, or regulations do not provide clear guidance or limits will be based on the purpose of the monuments, the range of public expectations and concerns, resource analysis, an evaluation of the natural, cultural, and social impacts of alternative courses of action, and consideration of long-term economic costs. Based on determinations of desired conditions, the general management plan will outline the kinds of resource management activities, visitor activities, and development that would be appropriate in the monuments in the future. Alternatives will be developed through this planning process and will include, at a minimum, the no-action and preferred alternative.

Major issues include protection of natural and cultural resources, providing for visitor enjoyment and understanding, and evaluating potential boundary expansions. Potential partnerships will be explored with other agencies, organizations, and local interests.

DATES: The National Park Service will conduct public scoping for 60-days from the date of publication of this notice in the **Federal Register**. Open houses regarding the general management plan will be held during the public scoping period. Specific dates, times, and locations will be announced in the local media and will also be available by contacting the superintendent of Montezuma Castle and Tuzigoot National Monuments.

ADDRESSES: Throughout the scoping and planning process, information will be available for public review and comment in the office of the superintendent (Kathy M. Davis, Montezuma Castle and Tuzigoot National Monuments, PO Box 219, Camp Verde, AZ 86322–0219).

FOR FURTHER INFORMATION CONTACT: Superintendent Kathy M. Davis, Montezuma Castle and Tuzigoot National Monuments, PO Box 219, Camp Verde, AZ 86322–0219: TEL (928) 567–5276; FAX: (928) 567–3597; e-mail: *kathy_m_davis@nps.gov.*

SUPPLEMENTARY INFORMATION: If you wish to comment on the general management planning process for Montezuma Castle and Tuzigoot National Monuments, or on any issues associated with the plan, you may submit your comments by any one of several methods. You may mail comments to Superintendent Kathy M. Davis, Montezuma Castle and Tuzigoot National Monuments, PO Box 219, Camp Verde, AZ 86322–0219. You may also e-mail comments to *kathy_m_davis@nps.gov.* You may also hand-deliver comments to the Montezuma Castle and Tuzigoot National Monuments visitor centers. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your address, you must state this prominently at the beginning of your comments. We will make all submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses available for public inspection in their entirety.

Dated: May 1, 2003.

Karen P. Wade,

Director, Intermountain Region.

[FR Doc. 03–13339 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–EJ–P

DEPARTMENT OF THE INTERIOR

National Park Service

Elk and Vegetation Management Plan, Environmental Impact Statement, Rocky Mountain National Park, Colorado

AGENCY: National Park Service, Interior.

ACTION: Notice of Intent to prepare an Environmental Impact Statement for the Elk and Vegetation Management Plan, Rocky Mountain National Park.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C 4332(C), the National Park Service is preparing an Environmental Impact Statement for the Elk and Vegetation Management Plan for Rocky Mountain National Park, Colorado. This effort will result in a plan for adaptively managing elk and vegetation that addresses important environmental and social

issues in the Rocky Mountain National Park area. Rocky Mountain National Park is the lead agency and the final decision will be made by the Regional Director, Intermountain Region. Because of the regional nature of issues concerning management of the migratory elk herd, the park has joined with the following agencies to create an interagency planning team: Town of Estes Park, Estes Valley Recreation and Parks District, Colorado Division of Wildlife, Arapaho-Roosevelt National Forest, U.S. Bureau of Reclamation, Town of Grand Lake, Grand County, and Larimer County. Consultations are ongoing with the Northern Arapaho and Northern Ute Tribes.

The appropriate population size and associated effects of elk in Rocky Mountain National Park and the Town of Estes Park have been intensely debated since the 1930s. The current elk population size is about 3,000 animals. Recent research results indicate that the elk population size, distribution, and migratory patterns are outside the range of variability that would be expected under natural conditions. This has resulted largely because the influence of any significant predation (including hunting) is missing from the system. All major, natural predators of elk were gone from the area by the early 1900s; and hunting on adjacent U.S. Forest Service and private lands has become largely ineffective due to extensive land development in and around Estes Park and elk habituation to residential areas.

The increase in the size and concentration of the elk population is resulting in a number of adverse effects in the area.

To date, the planning team has done some preliminary work to identify the purpose and need of an Elk and Vegetation Management Plan, as well as management tools that the agencies could potentially use to address specific needs. The planning team has not yet created alternatives and will draw heavily on the public input to both modify work to date and begin to build alternatives. The ''need for action'' summarizes the existing problems; *e.g.*, it explains why the agencies are taking action at all:

> The National Park Service is obliged by law and policy to maintain and restore, to the extent possible, natural conditions and processes in park units. The elk herd in the vicinity of Rocky Mountain National Park and Estes Park is larger, less migratory, and more concentrated than it would be under natural conditions. As a result, aspen and willow communities, which support high levels of biodiversity, are declining on the winter range, and grasslands are grazed at extremely high levels. The herd concentrates in safe areas of the Park and Estes Park in the winter, where elk strip vegetation, cause property damage, and pose an increasing threat to tourists and residents as the numbers of encounters between elk and humans increase. Additional impacts include the drain on agency resources, as staff is called in to help manage human/elk conflicts.

Purpose is an overarching statement of what the plan must do to be considered a success. The team has identified the following as the purpose of the Elk and Vegetation Management Plan:

> Reduce the impacts of elk on vegetation, as well as human/elk conflicts, and restore, to the extent possible, the natural range of variability in both the elk population and affected plant communities, while providing for elk viewing opportunities, associated recreational opportunities, and economic benefits.

Some of the specific issues that the plan is likely to address include: the size and distribution of the elk population; disrupted migration patterns; aspen and willow declines on the core winter range; locally high levels of herbivory; impacts on biodiversity; the risk of elk to human safety; damage to private property; lack of major natural predators; limited access to areas outside the Park that are open to hunting; traffic congestion and motor vehicle accidents; the importance of elk viewing to park visitors and local residents; maintaining recreational opportunities associated with elk (*e.g.*, viewing, hunting); the significance of the elk herd to tourism and local economies; and the need for consistency with interagency objectives for managing chronic wasting disease. Additional issues will be identified by the public during the scoping process.

The planning team is committed to involving the interested and affected public in working through preliminary work to date, as well as future components of the planning process. This includes framing an appropriate range of alternatives. Although the team has not created alternatives, it has identified some management tools that may be useful in resolving the problems and planning issues identified above. These tools include the use of barriers (*e.g.*, fences, rock/log piles), hazing (*e.g.*, cracker shells or other noisemaking devices, rubber bullets) or herding (*e.g.*, herding dogs, riders on horseback, people in golf carts, or people on foot with elk sticks), chemical repellents, habitat improvement in strategic locations, vegetation manipulation (*e.g.*, cutting, planting, prescribed fire), water manipulations (*e.g.*, reestablishing beaver, creating artificial dams), predator reintroduction, fertility control, hunting, and agency culling. Some of these tools would be more effective than others, and some would have more serious environmental consequences than others. Analysis of both effectiveness and impacts will be part of the Environmental Impact Statement.

As noted above, the agencies consider public participation and input to be key in the planning and environmental impact analysis process guiding preparation of the Draft Elk and Vegetation Management Plan and Environmental Impact Statement. Therefore, the planning team will offer several opportunities for education and involvement as part of scoping. A scoping brochure and webpage linked to the Rocky Mountain National Park Internet site (*http://www.nps.gov/romo/*) will be available by summer 2003. The scoping brochure and webpage will provide background information, describe the planning process, and identify opportunities for public involvement. The scoping brochure will be distributed to all parties on the project mailing list as well as other potentially interested stakeholders that are identified. The planning team will also conduct public scoping meetings, which at this time are anticipated in the summer of 2003. Specific dates, times, and locations will be announced in the local and regional news media and on the webpage and will be available by contacting Vaughn Baker, Superintendent of Rocky Mountain National Park.

DATES: The Park Service will accept comments from the public through August 27, 2003.

ADDRESSES: All interested parties are encouraged to provide written comments that identify concerns and issues associated with the Elk and Vegetation Management Plan or provide other relevant information. Comments may be mailed or hand-delivered to Vaughn Baker, Superintendent, Rocky Mountain National Park, 1000 U.S. Highway 36, Estes Park, Colorado 80517–8397. Comments may also be faxed to (970) 586–1397, or e-mailed to *ROMO_Superintendent@nps.gov.*

FOR FURTHER INFORMATION OR TO BE ADDED TO THE PROJECT MAILING LIST CONTACT: Therese Johnson, Management Biologist, Rocky Mountain National Park, 1000 U.S. Highway 36, Estes Park, Colorado 80517–8397, (970) 586–1262, Fax (970) 586–1359, or e-mail *Therese_Johnson@nps.gov.*

SUPPLEMENTARY INFORMATION: All comments that are submitted will become part of the public record. Please submit Internet comments as an ASCII

file avoiding the use of special characters and any form of encryption. Please also include ''ATTN: Elk'' and your name and return address in your Internet message. If you do not receive a confirmation from the system that we received your Internet message, contact Therese Johnson (970) 586–1262. The National Park Service will make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that their home address be withheld from the record, which will be honored to the extent allowable by law. There also may be circumstances in which the National Park Service would withhold from the record a respondent's identity, as allowable by law. If a respondent wishes the National Park Service to withhold their address, they must state this prominently at the beginning of the comment. The National Park Service will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Dated: April 30, 2003.

Karen Wade,

Director, Intermountain Region, National Park Service.

[FR Doc. 03–13338 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–CP–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent To Prepare a General Management Plan and Environmental Impact Statement

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the National Park Service announces its intent to prepare a General Management Plan and Environmental Impact Statement (GMP/EIS) for the Statue of Liberty National Monument and Ellis Island, New Jersey and New Jersey and New York. The park comprises Liberty Island (12.5 acres), site of the ''Statue of Liberty Enlightening the World'', and Ellis Island (27.5 acres), containing the Immigration Museum and other historic structures that formed the immigration station. Prepared by planners in the NPS Northeast Region, with assistance from advisors and consultants, the GMP/EIS will propose a long-term approach to managing the Statue of Liberty National Monument and Ellis Island. Consistent with the monument's mission, NPS policy, and other laws and regulations, alternatives will be developed to guide the management of the monument over the next 15 to 20 years. The alternatives will incorporate various zoning and management prescriptions to ensure resource preservation and public enjoyment of the monument. The environmental consequences that could result from implementing the various alternative will be evaluated in the plan. Impact topics will include cultural and natural resources, visitor experience, park operations, the socioeconomic environment, impairment, and sustainability. The public will be invited to express concerns about the management of the monument early in the process through public meetings and other media; and will have an opportunity to review and comment on a draft GMP/EIS. Following public review processes outlined under NEPA, the final plan will become official, authorizing implementation of a preferred alternative. the target date for the Record of decision is March 2006.

FOR FURTHER INFORMATION CONTACT: Superintendent, Statue of Liberty National Monument and Ellis Island, New York, (212) 363–3206.

Dated: April 21, 2003.

Cynthia Garrett,

Acting Superintendent, Statue of Liberty National Monument and Ellis Island.

[FR Doc. 03–13330 Filed 5–28–03; 8:45 am]

BILLING CODE 4310–6E–M

DEPARTMENT OF THE INTERIOR

National Park Service

Boston Harbor Islands Advisory Council; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463) that the Boston Harbor Islands Advisory Council will meet on Wednesday, September 3, 2003. The meeting will convene at 6 p.m. at the New England Aquarium Conference Center, Central Wharf, Boston, MA.

The Advisory Council was appointed by the Director of National Park Service pursuant to Public Law 104–333. The 28 members represent business, educational/cultural, community and environmental entities; municipalities surrounding Boston Harbor; Boston Harbor advocates; and Native American interests. The purpose of the Council is to advise and make recommendations to the Boston Harbor Islands Partnership with respect to the development and implementation of a management plan and the operations of the Boston Harbor Islands national park area.

The Agenda for this meeting is as follows:

1. Call to Order, Introductions of Advisory Council members present
2. Review and approval of minutes of the June meeting
3. Outreach program
4. Review or summer operations
5. Report from the NPS
6. Public Comment
7. Next Meetings
8. Adjourn

The meeting is open to the public. Further information concerning Council meetings may be obtained from the Superintendent, Boston Harbor Islands. Interested persons may make oral/written presentations to the Council or file written statements. Such requests should be made at least seven days prior to the meeting to: Superintendent, Boston Harbor Islands NRA, 408 Atlantic Avenue, Boston, MA 02110, telephone (617) 223–8667.

Dated: April 30, 2003.

George E. Price, Jr.,

Superintendent, Boston Harbor Islands NRA.

[FR Doc. 03–13326 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–52–M

DEPARTMENT OF THE INTERIOR

National Park Service

Boston Harbor Islands Advisory Council; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463) that the Boston Harbor Islands Advisory Council will meet on Wednesday, June 4, 2003. The meeting will convene at 4 pm at the New England Aquarium Conference Center, Central Wharf, Boston, MA.

The Advisory Council was appointed by the Director of National Park Service pursuant to Public Law 104–333. The 28 members represent business, educational/cultural, community and environmental entities; municipalities surrounding Boston Harbor; Boston Harbor advocates; and Native American interests. The purpose of the Council is to advise and make recommendations to the Boston Harbor Islands Partnership with respect to the development and implementation of a management plan and the operations of the Boston Harbor Islands national park area.

The Agenda for this meeting is as follows:

1. Call to Order, Introductions of Advisory Council members present
2. Review and approval of minutes of the March meeting
3. Update on outreach program

4. Finalize the nomination process
5. Report from the NPS
6. Public Comment
7. Next Meetings
8. Adjourn

The meeting is open to the public. Further information concerning Council meetings may be obtained from the Superintendent, Boston Harbor Islands. Interested persons may make oral/written presentations to the Council or file written statements. Such requests should be made at least seven days prior to the meeting to: Superintendent, Boston Harbor Islands NRA, 408 Atlantic Avenue, Boston, MA 02110, telephone (617) 223–8667.

Dated: April 30, 2003.

George E. Price, Jr.,

Superintendent, Boston Harbor Islands NRA.

[FR Doc. 03–13327 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–52–M

DEPARTMENT OF THE INTERIOR

National Park Service

Chalmette Battlefield Task Force Committee meeting

AGENCY: Jean Lafitte National Historical Park and Preserve, National Park Service.

ACTION: Notice of Task Force meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act, 5 U.S.C. App.1, Section 10(a)(2), that a meeting of the Chalmette Battlefield Task Force Committee will be held at 3 p.m. at the following location and date:

DATES: Wednesday, May 28, 2003.

ADDRESSES: Jean Lafitte National Historical Park and Preserve, Chalmette National Battlefield, 8606 West Saint Benard Highway, Chalmette, Louisiana 70043–4204.

FOR FURTHER INFORMATION CONTACT: Ms. Geraldine Smith, Superintendent, Jean Lafitte National Historical Park and Preserve, 419 Rue Decatur Street, New Orleans, Louisiana 70130, 504–589–3882, extension 137 or 108.

SUPPLEMENTARY INFORMATION: The purpose of the Chalmette Battlefield Task Force Committee is to advise the Secretary of the Interior on suggested improvements at the Chalmette Battlefield site within Jean Lafitte National Historical Park and Preserve. The members of the Task Force are as follows: Ms. Elizabeth McDougall, chairperson, Ms. Faith Moran, Mr. Anthony A. Fernandez, Jr., Mr. Drew Heaphy, Mr. Alvin W. Guillot, Mrs. George W. Davis, Mr. Eric Cager, Mr. Paul V. Perez, Captain Bonnie Pepper Cook, vice-chairperson, Mr. Michael L. Fraering, Colonel John F. Pugh, Jr., and Ms. Geraldine Smith.

The matters to be discussed at this meeting will include an onsite tour of the Chalmette Battlefield and Chalmette National Cemetery, history of the area, cultural landscape recommendations, and current citizens concerns and issues. This meeting will be open to the public; however, facilities and space for accommodating members of the public are limited. Any member of the public may file with the committee a written statement concerning the matters to be discussed. Written statements may also be submitted to the superintendent at the address above. Minutes of the meeting will be available at park headquarters for public inspection at 419 Decatur Street, New Orleans, Louisiana, for public inspection approximately 4 weeks after the meeting and on the park web-site at *http://www.nps.gov/jela.htm.*

Dated: April 9, 2003.

W. Thomas Brown,

Acting Regional Director, Southeast Region.

[FR Doc. 03–13335 Filed 5–28–03; 8:45 am]

BILLING CODE 4310–06–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Park System Advisory Board; Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

Notice is hereby given in accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix, that the National Park System Advisory Board will meet June 10–11, 2003, in Cuyahoga Falls, Ohio. On June 10, the Board will tour Cuyahoga Valley National Park areas and will be briefed regarding environmental, education and partnership programs. On June 11, the Board will convene its business meeting at 8:30 a.m., in the Portage Room (lobby level) of the Sheraton Suites—Akron/Cuyahoga Falls, 1989 Front Street, Cuyahoga Falls, Ohio 44221, telephone 330–929–3000. The meeting will be adjourned at 5 p.m. During the morning session, National Park Service Director Fran Mainella will greet the Board, followed by the report of the Board's National Landmarks Committee and the Board's consideration of National Historic Landmark nominations. In the afternoon, the Board will receive reports from its National Parks Science Committee, Education Committee, Strategic Communications Committee, and Partnerships Committee, and will discuss pending business.

Other officials of the National Park Service and the Department of the Interior may address the Board, and other miscellaneous topics and reports may be covered. The order of the agenda may be changed, if necessary, to accommodate travel schedules or for other reasons.

The Board meeting will be open to the public. Space and facilities to accommodate the public are limited and attendees will be accommodated on a first-come basis. Anyone may file with the Board a written statement concerning matters to be discussed. The Board may also permit attendees to address the Board, but may restrict the length of the presentations, as necessary to allow the Board to complete its agenda within the allotted time.

Anyone who wishes further information concerning the meeting, or who wishes to submit a written statement, may contact Mr. Loran Fraser, Office of Policy, National Park Service; 1849 C Street, NW., Room 7250; Washington, DC 20240; telephone 202–208–7456.

Draft minutes of the meeting will be available for public inspection about 12 weeks after the meeting, in room 7252, Main Interior Building, 1849 C Street, NW., Washington, DC.

Dated: May 5, 2003.

Loran Fraser,

Chief, Office of Policy.

[FR Doc. 03–13336 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before May 3, 2003. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St. NW., 8th floor, Washington DC 20005; or by fax, 202–

371–6447. Written or faxed comments should be submitted by June 13, 2003.

Carol D. Shull,

Keeper of the National Register of Historic Places.

COLORADO

Douglas County

Devils Head Lookout, South Platte District, Pike National Forest, Sedalia, 03000518.

LOUISIANA

Orleans Parish

Broadmoor Historic District, Roughly bounded by South Broad/Fountainbleau, Milan, S. Claiborne and Octavia, New Orleans, 03000519.

MINNESOTA

Hennepin County

Lock and Dam No. 2, Mississippi R N of Lake St/Marshall Ave., Minneapolis, 03000522.

Le Sueur County

Dodd Road Discontiguous District, Roughly Cty Rd. 1 to MN 21, Cty Rd. 136 W of Kilkenny cont. NW to Cty Rd. 2, Cty Rd. 148 W of Cleveland., Forest, 03000520.

St. Louis County

Pyhala, Anna and Mikko, Farm, (Rural Finnish Log Buildings of St. Louis County, Minnesota, 1890–1930s MPS) 4745 Salo Rd., Embarrass, 03000521.

MISSOURI

Jackson County

Exchange Building, 1201–1207 Grand Blvd., Kansas City, 03000524.

Greenlease Cadillac Building, 2900 Gillham Rd., Kansas City, 03000523.

Knickerbocker Apartments, 501–535 Knickerbocker Place, Kansas City, 03000525.

NEW HAMPSHIRE

Grafton County

Greenleaf, Abbie, Library, 439 Main St., Franconia, 03000526.

PENNSYLVANIA

Delaware County

Booth Farm, 3221 Foulk Rd., Boothwyn, 03000527.

Philadelphia County

Philadelphia School of Occupational Therapy, 419 S. 19th St., Philadelphia, 03000528.

A request for REMOVAL has been made for the following resources:

MINNESOTA

Rice County

Church of St. Patrick—Catholic (Rice County MRA), Co. Hwy. 10 (Dodd Rd.), Faribault (vicinity), 82003032.

Scott County

Roehl-Lenzmeier House (Scott County MRA), MN 300 Shakopee (vicinity), 80002170.

St. Louis County

Hearding, John Harris, Grammar and High School and John A. Johnson Grammar School Jct. Of 4th Ave. N and First St. W, Aurora, 96001593.

[FR Doc. 03–13337 Filed 5–28–03; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Notice of Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a registration under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with section 1301.34 of title 21, Code of Federal Regulations (CFR), notice is hereby given that on June 25, 2002, Johnson Matthey, Inc., Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, New Jersey, 08066, made application by renewal to the Drug Enforcement Administration to be registered as an importer of Phenylacetone (8501), a basic class of controlled substance listed in Schedule II.

The firm plans to import Phenylacetone for conversion to amphetamine base to sell in bulk to its customers.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative (CCD), and must be filed no later than June 30, 2003.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745–46 (September 23, 1975), all applicants for registration to import basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: April 29, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–13312 Filed 5–28–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to section 1301.33(a) of title 21 of the Code of Federal Regulations (CFR), this is notice that on January 6, 2003, Lonza Riverside, 900 River Road, Conshohocken, Pennsylvania 19428, made application by renewal and on April 14, 2003, by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Gamma hyrdoxybutyric acid (2010).	I
Amphetamine (1100)	II
Phenylacetone (8501)	II
Methyphenidate (1724)	II

The firm plans to produce bulk products and finished dosage units for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative, Office of Chief Counsel (CCD) and must be filed no later than July 28, 2003.

Dated: May 7, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–13309 Filed 5–28–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to section 1301.33(a) of title 21 of the Code of Federal Regulations (CFR), this is notice that on March 25, 2003, Organichem Corporation, 33 Riverside Avenue, Rensselaer, New York 12144, made application by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basis class of Schedule II of controlled substance listed below:

Drug	Schedule
Dextropoxyphene (9273)	II

The firm plans to manufacture bulk products for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substance may file comments or objection to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative (CCD) and must be filed no later than July 28, 2002.

Dated: April 29, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Officer of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–13311 Filed 5–28–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to section 1301.33(a) of title 21 of the Code of Federal Regulations (CFR), this is notice that on June 10, 2002, Organix, Inc., 240 Salem Street, Woburn, MA 01810, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic class of Cocaine (9041), a Schedule II controlled substance.

The firm plans to synthesize a controlled substance derivative from a non-controlled substance; the derivative will be sold to the firm's customer for research purposes.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCD) and must be filed no later than July 28, 2003.

Dated: May 7, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–13310 Filed 5–28–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to section 1301.33(a) of title 21 of the Code of Federal Regulations (CFR), this is notice that on January 28, 2003, Roche Diagnostics Corporation, Attn: Regulatory Compliance, 9115 Hague Road, Indianapolis, Indiana 46250, made application by renewal and on January 29, 2003, by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Lysergic Acid Diethylamide (7315)	I
Tetrahydrocannabinol (7370)	I
Alphamethadol (9605)	I
Phencyclidine (7471)	II
Benzoylecogonine (9180)	II
Methadone (9250)	II
Morphine (9300)	II

The firm plans to manufacture small quantities of controlled substances for use in diagnostic products.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative, Office of chief Counsel (CCD) and must be filed no later than July 28, 2003.

Dated: May 2, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–13313 Filed 5–28–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances, Notice of Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a registration under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with section 1301.34 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on January 28, 2003, Roche Diagnostics Corporation, 9115 Hague Road, Indianapolis, Indiana 46250, made application by renewal to the Drug Enforcement Administration to be registered as an importer of Schedules I & II, for the basic classes of controlled substances listed below:

Drug	Schedule
Lysergic Acid Diethylamide (7315)	I
Tetrahydrocannabinol (7370)	I
Alphamethadol (9605)	I
Phencyclidine (7471)	II
Benzoylecogonine (9180)	II
Methadone (9250)	II
Morphine (9300)	II

The firm plans to import the listed controlled substances to manufacture diagnostic products for distribution to its customers.

Any manufacturer holding, or applying for, registration as a bulk

manufacturer of any of these basic classes of controlled substances may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative, Office of Chief Counsel (CCD) and must be filed no later than June 30, 2003.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 301.34(b), (c), (d), (e), and (f).

As noted in a previous notice at 40 FR 43745–46 (September 23, 1975), all applicants for registration to import basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: May 2, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–13314 Filed 5–28–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By notice dated April 11, 2002, and published in the **Federal Register** on April 26, 2002 (67 FR 20828), Salsbury Chemicals, Inc., 1205 11th Street, Charles City, Iowa 50616–3466, made application by renewal to the Drug Enforcement Administration to be registered as a bulk manufacturer of Amphetamine (1100) and Methylphenidate (1724), both Schedule II controlled substances. The firm's legal name has since changed to Cambrex Charles City, Inc.

The firm plans to manufacture amphetamine and methylphenidate for distribution as bulk product to its customers.

No comments or objections have been received. DEA has considered the factors in title 21, United States Code, section 823(a) and determined that the registration of Cambrex Charles City, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Cambrex Charles City, Inc. to ensure that the company's registration is consistent with the public interest. This investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed is granted.

Dated: May 7, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 03–13308 Filed 5–28–03; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Office of Disability Employment Policy

[SGA 03–08]

Home Modification Grants

AGENCY: Office of Disability Employment Policy, Department of Labor.

ACTION: Notice of availability of funds; solicitation for grant applications (SGA).

This notice contains all of the necessary information and forms needed to apply for grant funding. (SGA 03–08).

SUMMARY: The U.S. Department of Labor (DOL), the Office of Disability Employment Policy (ODEP) announces the availability of $500,000 to award up to ten competitive grants in the amount of $50,000 to $100,000 each to provide home modifications as a means of further expanding the community integration of individuals with disabilities, and particularly those seeking employment. Grants will be awarded for a 12-month period of performance. After one year of support, it is anticipated that the grantees will have identified and developed the funds and resources needed to continue the expansion of such home modification programs within their respective localities.

For people with disabilities and older Americans, an often-cited barrier to participation in work and community life is the lack of affordable home modifications, such as ramps, widened doorways, lowered countertops and cabinetry accessible to those who use wheelchairs. Such modifications can often mean the difference between working and being unemployed, between being a taxpayer and a recipient of public assistance, and between true presence and participation in one's community and living in a nursing home. In *Olmstead* v. *L.C.,* 527 U.S. 581, 119 S.Ct. 2176 (1999) (the ''*Olmstead* decision''), the Supreme Court construed Title II of the Americans with Disabilities Act (ADA) to require states to place qualified individuals with mental disabilities in community settings, rather than in institutions, whenever treatment professionals determine that such placement is appropriate, the affected persons do not oppose such placement, and the state can reasonably accommodate the placement, taking into account the resources available to the state and the needs of others with disabilities.

In *Olmstead,* the Supreme Court stated that institutional placements of people with disabilities who can live in, and benefit from, community settings perpetuates the unwarranted assumptions that persons so isolated are incapable or unworthy of participating in community life. The Supreme Court stated that ''recognition that unjustified institutional isolation of persons with disabilities is a form of discrimination reflect[ed] two evident judgements'': (1) ''institutional placements of people with disabilities who can live in, and benefit from, community settings perpetuates the unwarranted assumptions that persons so isolated are incapable or unworthy of participating in community life''; and (2) ''confinement in an institution severely diminishes everyday life activities of individuals, including family relations, social contacts, *work options, economic independence,* educational advancement, and cultural enrichment.'' *Olmstead*, 119 S.Ct. 2176, 2179, 2187 [emphasis added]. This decision affects not only all persons in institutions and segregated settings, but also people with disabilities who are at risk of institutionalization, including people with disabilities on waiting lists to receive community based services and supports. The President has made it very clear, through his New Freedom

Initiative and through his Executive Order to Federal Agencies on the implementation of the *Olmstead* decision, that every effort should be expended to ensure that people can live and work in their communities and are not forced to live in congregate facilities and to give up any hope of employment.

The purpose of these grants, therefore, is to encourage the development of home modifications as a means to support individuals with disabilities as they seek and maintain employment.

DATES: Applications will be accepted May 29, 2003. The closing date for receipt of applications under this announcement is July 14, 2003. Applications must be received by 4:45 p.m. (ET) at the address below. No exceptions to the mailing and hand-delivery conditions set forth in this notice will be granted. Applications that do not meet the conditions set forth in this notice will be considered non-responsive.

ADDRESSES: Applications shall be mailed to: U.S. Department of Labor, Procurement Services Center, Attention: Cassandra Willis, Reference SGA 03–08, Room N–5416, 200 Constitution Avenue, NW., Washington, DC 20210. Telefacsimile (Fax) applications will not be accepted. Applicants are advised that mail delivery in the Washington area may be delayed due to mail decontamination procedures.

FOR FURTHER INFORMATION CONTACT: Cassandra Willis, U.S. Department of Labor, Procurement Services Center, telephone (202) 693–4570 (this is not a toll-free number), prior to the closing deadline. Persons who are deaf or hard of hearing may contact DOL via the Federal Relay Service, (800) 877–8339. This announcement will also be published on the Internet on the ODEP's online Home Page at: *http://www2.dol.gov/odep.* Award notifications will also be published on the ODEP Homepage.

SUPPLEMENTARY INFORMATION:

Part I. Delivery of Applications

1. Late Applications

Any application received after the exact date and time specified for receipt at the office designated in this notice will be considered non-responsive, unless it is received before awards are made and it (a) is determined that its late receipt was caused by DOL error; (b) was sent by U.S. Postal Service registered or certified mail not later than the fifth calendar day before the date specified for receipt of applications (*e.g.,* an application submitted in response to a solicitation requiring receipt of applications by the 20th of the month must have been post marked by the 15th of that month); or (c) was sent by the U.S. Postal Service Express Mail Next Day Service to addressee not later than 5 p.m. at the place of mailing two working days prior to the date specified for receipt of applications. The term ''working days'' excludes weekends and Federal holidays. ''Post marked'' means a printed, stamped or otherwise placed impression (exclusive of a postage meter machine impression) that is readily identifiable, without further action, as having been supplied or affixed on the date of mailing by an employee of the U.S. Postal Service.

2. Withdrawal of Applications

Applications may be withdrawn by written notice or telegram (including mail gram) received at any time before an award is made. Applications may be withdrawn in person by the applicant or by an authorized representative thereof, if the representative's identity is made known and the representative signs a receipt of the proposal.

3. Hand-Delivered Proposals

It is preferred that applications be mailed at least five days prior to the closing date. To be considered for funding, hand-delivered applications must be received by 4:45 p.m., ET, at the specified address. Failure to adhere to the above instructions will be basis for a determination of non-responsiveness. Overnight express mail from carriers other than the U.S. Postal Service will be considered hand-delivered applications and must be received by the above specified date and time.

Part II. Authority

Omnibus Appropriations Resolution, 2003, Public Law 1087; Consolidated Appropriations Act, 2001, Public Law 106–554, 29 U.S.C. 557b.

Part III. Background and Purpose

Background

Based on the 1995 American Housing Survey, almost 8.9 million housing units in the United States had at least one occupant who had a physical activity limitation—approximately 9.1 percent of the 97.7 million occupied housing units that year. It is estimated that as many as 3.4 million (38.4 percent) of homes with at least one occupant with activity limitations had some type of home modification (such as grab bars and ramps). In 3.3 million (36.9 percent) of the homes, an occupant with activity limitations received help from another person. Canes, walkers, or crutches were used in 3.4 million (37.9 percent) of the homes; wheelchairs, 1.4 million (15.3 percent); motorized or electric carts, 161,000 (1.8 percent); and other devices, 462,000 (5.2 percent). Approximately 5.1 million (57.4 percent) of the households in which a member had an activity limitation had no home modifications present.

In general, funding to meet this significant home modification need is scarce nationally and eligibility is often limited for the few programs available that help an individual in need of home modifications. Assistance through the Veterans Administration for some modifications, for example, is only available to eligible veterans. Some Centers for Independent Living provide funds for such purposes, but the funding is extremely limited and not widely available, particularly in rural areas. The Social Security Administration may allow deductions for the cost of certain modifications from earned income, but only to participants in certain work programs and if the modifications are deemed required for employment outcomes. Vocational Rehabilitation may also provide funding for some home modifications, but only for those eligible individuals seeking employment. The Fair Housing Act mandates that the landlord allow a tenant to make modifications, but usually at their own expense and with the responsibility to return the rental property to its original state upon termination of the lease. The Department of Housing and Urban Development's (HUD) Section 203(b) loan program allows funding to be used for home modifications, but many simply cannot afford such loans.

In many communities across the country, older Americans and people with disabilities must rely on faith-based and community organizations as well as charitable associations for such assistance. In many cases, such funding is simply not available at all. Often, individuals are, in essence, ''forced'' to leave their homes for nursing homes or assisted living facilities, or prevented from moving into otherwise affordable housing, due to such inaccessibility. Just as often, opportunities for employment must go unrealized due to an inability to leave one's house without great effort.

Purpose

Through the President's Faith-Based and Community Initiative (FBCI), local faith-based and community organizations can take a leadership role in assisting individuals with disabilities to remain in their homes, or to move into accessible homes. To coordinate this effort, DOL is partnering with the Corporation for National and

Community Service (CNCS) and HUD to promote the development of home modifications as a means to encourage the employment of individuals with disabilities. This unique partnership will allow the Federal government to promote both the spirit and the responsibilities of both the New Freedom Initiative and the *Olmstead* Executive Order, while concurrently recognizing the valuable community roles played by America's faith-based and community organizations. Moreover, it is the intention of this solicitation to assist individuals with disabilities to remain in their homes or move into accessible housing and thereby directly facilitate and provide these employment supports to further their opportunities to seek and retain employment and training in their communities.

Part IV. Funding Availability and Period of Performance

The ODEP anticipates awarding approximately up to ten competitive grants in the amount of $50,000 to $100,000 each to provide home modifications as a means of further expanding the community integration of individuals with disabilities, and particularly those seeking employment. Grants will be awarded for a 12-month period of performance. After one year of support, it is anticipated that the grantees will have identified and developed the funds and resources needed to continue the expansion of such home modification programs within their respective localities.

This solicitation calls for the creation of several local programs to provide home modifications to assist individuals with disabilities and older Americans to live and work in their communities. Funding will be provided for local organizations to purchase materials, analyze accessibility, and build the necessary modifications. These organizations are encouraged to seek donations of materials and labor from local businesses, labor organizations, and community associations. In addition, these organizations are also strongly encouraged to work with their local Centers for Independent Living and other disability advocacy organizations to determine local need and potential resources.

Part V. Eligible Applicants and Required Partnerships

Eligible Applicants

Eligible applicants include faith-based and community organizations that must be non-profit entities (although not 501(c)(4) entities subject to the Lobbying Disclosure Act) that also:

(1) Have social services as a major part of their mission;

(2) Are headquartered in the local community to which they provide these services; and

(3) Have a total annual operating budget of $300,000 or less, or have six (6) or fewer full-time equivalent employees.

Note: For purposes of this SGA, local affiliates of national social service organizations are not considered ''faith-based and community organizations'' and are not eligible to apply.

Part VI. Format Requirements for Grant Application

General Requirements

Applicants must submit one (1) paper copy with an original signature and two (2) additional paper copies of their signed proposal. To aid with the review of applications, USDOL also encourages Applicants to submit an electronic copy of their proposal on a disc or CD using Microsoft Word. Applicants who do not provide an electronic copy will not be penalized. The Application Narrative must be double-spaced with standard margins on 8½ x 11 papers, and be presented on single-sided, numbered pages with the exception of format requirements for the Executive Summary. The Executive Summary must be limited to no more than two single-spaced, single-sided pages on 8½ x 11 papers with standard margins throughout. A font size of at least twelve (12) pitch is required throughout. Applications that fail to meet these requirements will be considered non-responsive.

The three required sections of the application are:

Section I—Project Financial Plan
Section II—Executive Summary—Project Synopsis
Section III—Project Narrative (including Attachments, not to exceed 15 pages)

Mandatory requirements for each section are provided as follows in this application package. Applications that fail to meet the stated mandatory requirements of each section will be considered non-responsive.

Mandatory Application Requirements

- Section I. Project Financial Plan (Budget) [The Project Financial Plan will not count against the application page limits.] Section I of the application must include the following three required parts:

(1) Completed ''SF 424—Application for Federal Assistance'' (See Appendix A of this SGA for required form)

(2) Completed ''SF 424A—Budget Information Form'' by line item for all costs required to implement the project design effectively. (See Appendix B of this SGA for required forms.)

(3) Budget Narrative and Justification that provides sufficient information to support the reasonableness of the costs included in the budget in relation to the service strategy and planned outcomes.

The application must include one SF–424 with the original signatures of the legal entity applying for grant funding and 2 additional copies. Applicants shall indicate on the SF–424 the organization's IRS status, if applicable. Under the Lobbying Disclosure Act of 1995, Section 18 (29 U.S.C. 1611), an organization described in Section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities will not be eligible for the receipt of Federal funds constituting an award, grant, or loan. (*See* 2 U.S.C. 1611; 26 U.S.C. 501(c)(4).) For item 10 of the SF–424, the Catalog of Federal Domestic Assistance (CFDA) number for the program is 17.720.

The Budget Narrative and Justification must describe all costs associated with implementing the project that are to be covered with grant funds. Grantees must support the travel and associated costs with sending at least one representative to the annual ODEP Policy Conference for Grantees, to be held in Washington, DC, at a time and place to be determined. Grantees must comply with the ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments,'' (also known as the ''Common Rule'') codified at 29 CFR part 97, and must comply with the applicable OMB cost principles circulars, as identified in 29 CFR 95.27 and 29 CFR 97.22(b).

In addition, the budget must include on a separate page a detailed cost analysis of each line item. Justification for administrative costs must be provided. Approval of a budget by the DOL is not the same as the approval of actual costs. The individual signing the SF 424 on behalf of the applicant must represent and be able to legally bind the responsible financial and administrative entity for a grant should that application result in an award. The applicant must also include the Assurances and Certifications Signature Page (Appendix C).

- Section II. Executive Summary—Project Synopsis [The Executive Summary is limited to no more than two single-spaced, single-sided pages on 8½

x 11 papers with standard margins throughout]. Each application shall include a project synopsis that identifies the following:

(1) The name of the applicant;

(2) The type of organization the applicant represents, the additional consortium partners and the type of organization they represent;

(3) The amount of funds requested;

(4) The planned period of performance;

(5) An overview of the applicant's plan accomplishing the goals of Home Modification; and

(6) An overview of the applicant's plan for sustaining the Home Modification program once Federal funding ceases.

• Section III. Project Narrative [The Project Narrative plus attachments are limited to no more than fifteen (15) 8½ x 11 pages, double-spaced with standard one-inch margins (top, bottom, and sides), and be presented on single-sided, numbered pages. Note: The Financial Plan, the Executive Summary, and the Appendices are not included in the fifteen (15)-page limit]. The substantive requirements for the project narrative are described below under Part VII—Statement of Work.

All text in the application narrative, including titles, headings, footnotes, quotations, and captions, as well as all text in charts, tables, figures, and graphs must be double-spaced (no more than three lines per vertical inch); and, if using a proportional computer font, use no smaller than a 12-point font, and an average character density no greater than 18 characters per inch (if using a non-proportional font or a typewriter, do not use more than 12 characters per inch). Applications that fail to meet these requirements will be considered non-responsive.

Part VII. Government Requirements/ Statement of Work [Project Narrative]

The Project Narrative, or Section III of the grant application, should provide complete information on how the applicant will utilize an expanded capacity through this funding, to assess the need for home modifications for local residents with disabilities, and to arrange and complete those modifications. This system will better serve individuals with disabilities as they transition from facility-based residential sites to community housing, and to the work world. The period of performance will be 12 months from the date of execution by the Government. Up to ten competitive grants will be awarded in the range of $50,000 to $100,000. This grant program will target five to ten localities to conduct this effort. Each locality will be responsible for:

(1) Recruiting targeted recipients,

(2) Assessing the necessary modifications,

(3) Conducting the work,

(4) Arranging sufficient and appropriate press opportunities, and

(5) Submitting summaries of their respective activities.

The Project Narrative of the grant application must provide complete information that will address the requirements of this SGA, including significance of the proposed project. The Department, however, does not expect the applicant to incorporate every item listed as part of their strategy and proposal design. The Department recognizes that the needs and requirements of each locality may be different, and therefore, some of the options identified may be more relevant than others in a particular locality.

1. Significance of the Proposed Project (20 Points)

The purpose of the Significance of the Proposed Project is to assess the overall elements of the applicant's proposal; to identify strengths and deficiencies to be addressed by the applicant's proposal; to identify the overall scope of proposal objectives and design; and, to present the applicant's need for Home Modification grant resources. This criterion will be rated based upon the applicant's proposed approach to addressing identified community needs in the context of the grant priorities.

The Project Narrative must include:

(1) Evidence of significant previous involvement in the provision of home modifications for persons with disabilities or older Americans;

(2) Current and anticipated linkages with local disability-related organizations, such as Centers for Independent Living, vocational rehabilitation agencies, local governmental entities, faith-based and community organizations, and/or provider agencies; and

(3) Describe how individuals with disabilities from diverse cultures will be recruited for participation in this effort; demonstrate how special emphasis will be made on the recruitment of individuals who are seeking employment outcomes or who are currently working from home.

Positive press clippings and ''success stories'', if available, should also be included.

In determining the significance of the proposed project, ODEP will consider the following factors:

(a) The potential contribution of the proposed project to the employment of individuals with disabilities;

(b) The current level of similar activity in the applicant's locality and those sites commitment to work with this application;

(c) The extent to which the proposed project is likely to yield findings that may be used by other appropriate agencies and organizations;

(d) The extent to which the proposed project involves the development or demonstration of promising new strategies to expand home modification options for individuals with disabilities;

(e) The likely utility of the products (such as information, materials, processes, or techniques) that will result from the proposed project; and

(f) The importance or magnitude of the results likely to be attained by the proposed project.

2. Quality of the Project Design (30 Points)

The purpose of the Quality of the Project Design criteria is to identify the strategic plan proposed by the grantee to implement the Home Modification program in their locality. The application must address the proposed design for a locally based effort. The plan should identify:

(1) Local organizations' roles within the proposed activities, including faith-based and community organizations;

(2) How those organizations will integrate resources to advance the effort;

(3) The proposed plan for recruiting individuals with disabilities, especially those either seeking employment or currently working from home;

(4) Plans, if warranted, for long term funding for the initiative;

(5) Evidence of working with their local One-Stop Career Center(s) for purposes of outreach and referral.

(6) Provide an estimate of the type and extent of modifications, as well as the number of expected target recipients;

(7) Identify any matching funds, including federal housing funds (such as Community Development Block Grants and HOME Program funds), corporate funding, local governmental funding, etc., to be utilized; and

(8) Provide an estimate of expected donated materials as well as in-kind contributions, including volunteer time.

In evaluating the quality of the proposed project design, the ODEP will also consider the following factors:

(a) The extent to which the goals, objectives, and outcomes to be achieved are clearly specified and measurable;

(b) The extent to which the design of the proposed project features innovative

methods for developing new sites and/or strengthening existing sites;

(c) The extent to which the proposal incorporates a viable strategic plan;

(d) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the period of this grant;

(e) The extent to which the proposed budget and narrative justification are adequate to support the proposed project; and

(f) The extent to which the proposed project will be coordinated with similar or related efforts.

3. Sustainability Through Leveraging of Other Resources (25 Points)

The Project Narrative must describe a detailed plan for sustaining this project after grant funds cease. Projects funded under this SGA should leverage a combination of Federal, state, and local public sector resources, as well as local non-profit sector resources for purposes of sustainability.

The successful applicant will:

(1) Describe the strategy for gaining the support of area employers, people with disabilities and their family members, and local governmental and nongovernmental disability organizations;

(2) Identify federal, state, and local public sector resources, as well as local non-profit sector resources that will be leveraged for purposes of sustainability after the grant period ends;

(3) Document a willingness to cooperate with the ODEP and its technical assistance efforts to provide information and advice to other localities on how the home modifications activities can be replicated.

In evaluating the quality of the plan for sustainability, the DOL will also consider the following factors to be of particular importance:

(a) The extent to which public and private monies are leveraged effectively; and

(b) The likelihood of the applicant successfully securing local ownership and participation in these projects when these grant funds cease.

Grantees are expected to use this grant as seed money to develop other public and private resources in order to ensure sustainability of grant activities following completion of the funding period. The ODEP considers detailed commitments for specific new activities as more important than promises of in-kind supports in showing sustained support for the project. Grants recently received from another agency can be discussed in the proposal, but the applicant should be precise about which activities precede this grant and which will occur because of this grant. In addition, the applicant should detail how public sector commitments can contribute to the sustainability of this project following completion of the grant. Examples of the types of public and private sector commitments envisioned include the following:

Letters of Commitment

Applicants can include letters of support if they provide specific commitments. Such letters can increase an applicant's score by showing that the commitments in the text of the proposal are serious. Form letters will not be considered.

Letter From the Mayor

A letter from the Mayor or functionally equivalent entity reflecting support of local level participation in the Home Modifications Program will be viewed favorably.

4. Management, Outcomes and Personnel (25 Points)

The purpose of the Management, Outcomes and Personnel criteria is to determine whether the applicant has developed an adequate management and personnel plan to effectively carry out the objectives and scope of the proposed project on time and within budget, to describe the predicted outcomes resulting from activities funded under this SGA, and to identify the methods of evaluation that will be used by the grantee to determine success.

Successful applicants will provide a detailed management plan for project goals, objectives, personnel and activities that:

(1) Describes plans to report the demographic characteristics of assisted individuals (including types if disabilities);

(2) Provides a commitment to submit ''stories'' outlining the results of their efforts;

(3) Describes the proposed staffing of the project;

(4) Addresses staff capacity in relationship to the proposed project design;

(5) Identifies and summarizes the qualifications of the personnel, including the relevant training and experience of project consultants or subcontractors, who will carry out the work of the project. [Projects funded under this notice must demonstrate positive efforts to employ and advance in that employment qualified individuals with disabilities in project activities.]

In evaluating the quality of the management, outcomes and personnel plan for the proposed project; ODEP will consider the following factors:

(a) The extent to which the goals, objectives, and outcomes to be achieved are clearly specified and measurable;

(b) The extent to which a management plan for project implementation is likely to achieve the objectives of the proposed project on time and within budget, including defined staff responsibilities, and time allocated to project activities, time lines, milestones for accomplishing project tasks and project deliverables;

(c) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project; and,

(d) The extent to which the time commitments of the local director and/or and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(e) The qualifications, including relevant education, training and experience of key project personnel as well as the qualifications, including relevant training and experience, of project consultants or subcontractors.

Part VIII. Monitoring and Reporting

Monitoring

The ODEP is responsible for ensuring the effective implementation of each competitive grant project in accordance with the provisions of this announcement and the terms of the grant award document. The DOL staff, or their designees may conduct on-site project reviews periodically. Reviews will focus on timely project implementation, performance in meeting the grant's programmatic goals and objectives, expenditure of grant funds on allowable activities, integration and coordination with other resources and service providers in the local area, and project management and administration in achieving project objectives.

Reporting

Grantees will be required to submit quarterly financial and narrative progress reports as prescribed by OMB Circular A–102 and A–110, as codified by 29 CFR Parts 97 and 95 respectively.

(1) A Quarterly Report will be required within thirty (30) days of the end of each quarter beginning ninety days from the award of the grant and is estimated to take five hours to prepare on average. The form for the Quarterly Report will be provided by the ODEP. The ODEP will work with the grantee to help refine the requirements of the report, which will, among other things, include measures of ongoing analysis for continuous improvement and customer satisfaction.

(2) Financial reporting will be required quarterly using the on-line electronic reporting system for the Standard Form 269—Financial Status Report (FSR).

(3) A Final Project Report, including an assessment of project performance and outcomes achieved will be required and is estimated to take twenty hours to complete. This report will be submitted in hard copy and on electronic disk using a format and following instructions that will be provided by the ODEP. A draft of the final report is due to the ODEP thirty (30) days before the termination of the grant. The final report is due to the ODEP sixty (60) days following the termination of the grant.

The ODEP may arrange for and conduct an independent evaluation of the outcomes, impacts, and accomplishments of each funded project. Grantees must agree to make available records on all parts of project activity, including participant post secondary and employment data, and to provide access to personnel, as specified by the evaluator(s), under the direction of the ODEP. This independent evaluation is separate from the ongoing evaluation for continuous improvement required of the grantee for project implementation.

Grantees must also agree to work with the ODEP in its various technical assistance efforts in order to freely share with others what is learned about delivering customized employment services to the Olmstead population. Grantees must agree to collaborate with other research institutes, centers, studies, and evaluations that are supported by DOL and other relevant Federal agencies, as appropriate. Finally, Grantees must agree to actively utilize the programs sponsored by the ODEP, including the Job Accommodation Network, (*http://www.jan.wvu.edu*), and the Employer Assistance Referral Network (*http://www.earnworks.com*).

Part IX. Review Process and Evaluation Criteria

All applications will be reviewed for compliance with the requirements of this notice. A careful evaluation of applications will be made by a technical review panel, which will evaluate the applications against the rating criteria listed in this SGA. The panel results are advisory in nature and not binding on the Grant Officer. The DOL may elect to award grants either with or without discussion with the applicant. In situations without discussions, an award will be based on the applicant's signature on the SF 424, which constitutes a binding offer. The Grant Officer may consider any information that is available and will make final award decisions based on what is most advantageous to the Government, considering factors such as:

Panel findings;
Geographic distribution of the competitive applications; and
Availability of funds.

X. Administration Provisions

A. Administrative Standards and Provisions

Grantees are strongly encouraged to read these regulations before submitting a proposal. The grant awarded under this SGA shall be subject to the following as applicable:

- 29 CFR part 95—Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, and With Commercial Organizations, Foreign Governments, Organizations Under the Jurisdiction of Foreign Governments, and International Organizations;
- 29 CFR part 96—Audit Requirements for Grants, Contracts, and Other Agreements.

B. Allowable Cost

Determinations of allowable costs shall be made in accordance with the following applicable Federal cost principles:

- Nonprofit Organizations—OMB Circular A–122
- Profit-Making Commercial Firms—48 CFR part 31

Profit will not be considered an allowable cost in any case.

C. Grant Assurances

As a condition of the award, the applicant must certify that it will comply fully with the nondiscrimination and equal opportunity provisions of the following laws:

- 29 CFR part 31—Nondiscrimination in Federally-assisted programs of the Department of Labor, effectuation of Title VI of the Civil Rights Act of 1964.
- 29 CFR part 32—Nondiscrimination on the Basis of Disability in Programs and Activities Receiving or Benefiting from Federal Assistance. (Implementing section 504 of the Rehabilitation Act, 29 U.S.C. 794)
- 29 CFR part 36—Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance. (Implementing title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et. seq.*)

The applicant must include assurances and certifications that it will comply with these laws in its grant application. The assurances and certifications are attached as Appendix C.

Signed at Washington, DC, this 20th day of May, 2003

Lawrence J. Kuss,

Grant Officer.

Appendix A. Application for Federal Assistance, Form SF 424
Appendix B. Budget Information Sheet, Form SF 424A
Appendix C. Assurances and Certifications Signature Page
Appendix D. Survey on Ensuring Equal Opportunity

BILLING CODE 4510–CX–P

APPLICATION FOR FEDERAL ASSISTANCE

OMB Approval No. 0348-0043

2. DATE SUBMITTED	Applicant Identifier	
3. DATE RECEIVED BY STATE	State Application Identifier	
4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier	

1. TYPE OF SUBMISSION:

Application
☐ **Construction**
☐ **Non-Construction**

Preapplication
☐ **Construction**
☐ **Non-Construction**

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address *(give city, county, State, and zip code):*	Name and telephone number of person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER *(EIN):*

☐☐ — ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify) _____

8. TYPE OF APPLICATION:

☐ **New** ☐ **Continuation** ☐ **Revision**

If Revision, enter appropriate letter(s) in box(es) ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other*(specify):*

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

☐☐ — ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(Cities, Counties, States, etc.):*

13. PROPOSED PROJECT		**14. CONGRESSIONAL DISTRICTS OF:**	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:

a. Federal	$ .00
b. Applicant	$ .00
c. State	$ .00
d. Local	$ .00
e. Other	$ .00
f. Program Income	$ .00
g. TOTAL	$ 0.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. No. ☐ PROGRAM IS NOT COVERED BY E. O. 12372
☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ **Yes** **If "Yes," attach an explanation.** ☐ **No**

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.

a. Type Name of Authorized Representative	b. Title	c. Telephone Number
d. Signature of Authorized Representative		e. Date Signed

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Standard Form 424 (Rev. 7-97)
Prescribed by OMB Circular A-102

Appendix A

INSTRUCTIONS FOR THE SF-424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0043), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:
1.	Self-explanatory.
2.	Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).
3.	State use only (if applicable).
4.	If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5.	Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7.	Enter the appropriate letter in the space provided.
8.	Check appropriate box and enter appropriate letter(s) in the space(s) provided: -- "New" means a new assistance award. -- "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date. -- "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9.	Name of Federal agency from which assistance is being requested with this application.
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12.	List only the largest political entities affected (e.g., State, counties, cities).
13.	Self-explanatory.
14.	List the applicant's Congressional District and any District(s) affected by the program or project.
15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BUDGET INFORMATION - Non-Construction Programs

OMB Approval No. 0348-0044

SECTION A - BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$ 0.00
2.						0.00
3.						0.00
4.						0.00
5. Totals		$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION B - BUDGET CATEGORIES

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total
	(1)	(2)	(3)	(4)	(5)
a. Personnel	$	$	$	$	$ 0.00
b. Fringe Benefits					0.00
c. Travel					0.00
d. Equipment					0.00
e. Supplies					0.00
f. Contractual					0.00
g. Construction					0.00
h. Other					0.00
i. Total Direct Charges *(sum of 6a-6h)*	0.00	0.00	0.00	0.00	0.00
j. Indirect Charges					0.00
k. TOTALS *(sum of 6i and 6j)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
7. Program Income	$	$	$	$	$ 0.00

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Standard Form 424A (Rev. 7-97)
Prescribed by OMB Circular A-102

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SECTION C - NON-FEDERAL RESOURCES				
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$ 0.00
9.				0.00
10.				0.00
11.				0.00
12. TOTAL *(sum of lines 8-11)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$ 0.00	$	$	$	$
14. Non-Federal	0.00				
15. TOTAL *(sum of lines 13 and 14)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT				
(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.				
20. TOTAL *(sum of lines 16-19)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION F - OTHER BUDGET INFORMATION	
21. Direct Charges:	22. Indirect Charges:
23. Remarks:	

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Standard Form 424A (Rev. 7-97) Page 2

INSTRUCTIONS FOR THE SF-424A

Public reporting burden for this collection of information is estimated to average 180 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0044), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

Section A. Budget Summary Lines 1-4 Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the Catalog program title and the Catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the Catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the Catalog program title on each line in *Column* (a) and the respective Catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1-4, Columns (c) through (g)

For new applications, leave Column (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 - Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Line 6a-i - Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount, Show under the program

INSTRUCTIONS FOR THE SF-424A (continued)

narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal Resources

Lines 8-11 Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a) - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b) - Enter the contribution to be made by the applicant.

Column (c) - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d) - Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e) - Enter totals of Columns (b), (c), and (d).

Line 12 - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13 - Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14 - Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15 - Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16-19 - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20 - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21 - Use this space to explain amounts for individual direct object class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22 - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23 - Provide any other explanations or comments deemed necessary.

OMB Approval No. 0348-0040

ASSURANCES - NON-CONSTRUCTION PROGRAMS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0040), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

NOTE: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant, I certify that the applicant:

1. Has the legal authority to apply for Federal assistance and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project cost) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§4728-4763) relating to prescribed standards for merit systems for programs funded under one of the 19 statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. §§290 dd-3 and 290 ee 3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. §§3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and, (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally-assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply, as applicable, with provisions of the Hatch Act (5 U.S.C. §§1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

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Prescribed by OMB Circular A-102

Appendix C

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§276a to 276a-7), the Copeland Act (40 U.S.C. §276c and 18 U.S.C. §874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§327-333), regarding labor standards for federally-assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§1451 et seq.); (f) conformity of Federal actions to State (Clean Air) Implementation Plans under Section 176(c) of the Clean Air Act of 1955, as amended (42 U.S.C. §§7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended (P.L. 93-523); and, (h) protection of endangered species under the Endangered Species Act of 1973, as amended (P.L. 93-205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. §470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. §§469a-1 et seq.).

14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. §§2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§4801 et seq.) which prohibits the use of lead-based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act Amendments of 1996 and OMB Circular No. A-133, "Audits of States, Local Governments, and Non-Profit Organizations."

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

Standard Form 424B (Rev. 7-97) Back

Survey on Ensuring Equal Opportunity

Federal Agency Use Only

OMB No. 1225-0083 Exp. 02/28/2006

NOTE: Please place survey form directly behind the Standard Application for Federal Assistance (SF 424) fact sheet.

Purpose: This form is for applicants that are private nonprofit organizations (not including private universities). Please complete it to assist the federal government in ensuring that all qualified applicants, small or large, non-religious or faith-based, have an equal opportunity to compete for federal funding. Information provided on this form will not be considered in any way in making funding decisions and will not be included in the federal grants database.

1. Does the applicant have 501(c)(3) status?

❑ Yes ❑ No

2. How many full-time equivalent employees does the applicant have? *(Check only one box).*

❑ 3 or Fewer ❑ 15-50
❑ 4-5 ❑ 51-100
❑ 6-14 ❑ over 100

3. What is the size of the applicant's annual budget? *(Check only one box.)*

❑ Less Than $150,000
❑ $150,000 - $299,999
❑ $300,000 - $499,999
❑ $500,000 - $999,999
❑ $1,000,000 - $4,999,999
❑ $5,000,000 or more

4. Is the applicant a faith-based/religious organization?

❑ Yes ❑ No

5. Is the applicant a non-religious community-based organization?

❑ Yes ❑ No

6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?

❑ Yes ❑ No

7. Has the applicant ever received a government grant or contract (Federal, State, or local)?

❑ Yes ❑ No

8. Is the applicant a local affiliate of a national organization?

❑ Yes ❑ No

Appendix D

Survey Instructions on Ensuring Equal Opportunity for Applicants

1. 501(c) (3) statuses is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.

2. For example, two part-time employees who each work half time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.

3. Annual budget means the amount of money your organization spends each year on all of its activities.

4. Self-identify.

5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.

6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.

7. Self-explanatory.

8. Self-explanatory

Paperwork Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 1225-0083. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: Departmental Clearance Officer, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-1301, Washington, D.C. 20210. If you have comments or concerns regarding the status of your individual submission of this form, write directly to: Joyce I. Mays, Application Control Center, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.

[FR Doc. 03–13399 Filed 5–28–03; 8:45 am]
BILLING CODE 4510–CX–C

DEPARTMENT OF LABOR

Office of Disability Employment Policy

[SGA 03–07]

Working for Freedom, Opportunity and Real Choice Through Community Employment (WorkFORCE) Action Grant Initiative

AGENCY: Office of Disability Employment Policy, Department of Labor.

ACTION: Notice of availability of funds; solicitation for grant applications (SGA).

This notice contains all of the necessary information and forms needed to apply for grant funding. (SGA 03–07)

SUMMARY: The U.S. Department of Labor (DOL), Office of Disability Employment Policy (ODEP) announces the availability of $2.5 million to award up to 6 competitive Working for Freedom, Opportunity and Real Choice through Community Employment (WorkFORCE) Action Grant Initiative grants ranging from approximately $400,000 to $625,000 to continue its support for increasing and improving employment opportunities that allow individuals with disabilities to: (1) Move from nursing homes or other institutions and residential facilities into the community; (2) continue living in the community; (3) achieve economic self-sufficiency; and (4) attain full access to, and participation in their communities. These demonstration grants will begin or expand the delivery and implementation of customized community employment opportunities for individuals with disabilities so that they may live, work, and fully participate in their communities.

The purpose of these grants, therefore, is to develop and document the capability of individuals transitioning from segregated environments (such as nursing homes, institutions, and segregated day environments) to: (1) Successfully participate in community employment through utilization of customized strategies; (2) increase their earnings and economic power through participation in such employment; and (3) live, work and fully participate in their communities. The WorkFORCE Action Grants will be funded for a one-year period and may be renewed for a period of up to four additional years at varying funding levels (*see* Section IV) depending upon the availability of funds and the efficacy of the project activities.

The applicants scoring the highest when evaluated pursuant to the criteria set forth in Part VII, in conjunction with considerations by the Grant Officer delineated in Part IX of this Solicitation for Grant Application will be awarded WorkFORCE Action Grants.

Eligibility: Non-profit organizations, including faith-based and community organizations, working in coordination with the One-Stop delivery system, as provided under the Workforce Investment Act (WIA) (Pub. L. 105–220, 29 U.S.C. 2801 *et seq.*), are eligible applicants for WorkFORCE Action Grants.

DATES: Applications will be accepted on May 29, 2003. The closing date for receipt of applications under this announcement is July 14, 2003. Applications must be received by 4:45 p.m. (ET) at the address below. No exceptions to the mailing and hand-delivery conditions set forth in this notice will be granted. Applications that do not meet the conditions set forth in this notice will be considered non-responsive.

ADDRESSES: Applications shall be mailed to: U.S. Department of Labor, Procurement Services Center, Attention: Cassandra Willis, Reference SGA 03–07, Room N–5416, 200 Constitution Avenue, NW., Washington, DC 20210. Telefacsimile (Fax) applications will not be accepted. Applicants are advised that mail in the Washington area may be delayed due to mail decontamination procedures.

FOR FURTHER INFORMATION CONTACT: Cassandra Willis, U.S. Department of Labor, Procurement Services Center, telephone (202) 693–4570 (this is not a toll-free number), prior to the closing deadline. Persons who are deaf or hard of hearing may contact DOL via the Federal Relay Service, (800) 877–8339. This announcement will also be published on the Internet on the ODEP's online Home Page at: *http://www2.dol.gov/odep.* Award notifications will also be published on the ODEP homepage.

SUPPLEMENTARY INFORMATION:

Part I. Delivery of Applications

1. Late Applications

Any application received after the exact date and time specified for receipt at the office designated in this notice will be considered non-responsive, unless it is received before awards are made and it (a) is determined that its late receipt was caused by DOL error; (b) was sent by U.S. Postal Service registered or certified mail not later than the fifth calendar day before the date specified for receipt of applications (*e.g.*, an application submitted in response to a solicitation requiring receipt of applications by the 20th of the month must have been post marked by the 15th of that month); or (c) was sent by the U.S. Postal Service Express Mail Next Day Service to addressee not later than 5 p.m. at the place of mailing two working days prior to the date specified for receipt of applications. The term ''working days'' excludes weekends and Federal holidays. ''Post marked'' means a printed, stamped or otherwise placed impression (exclusive of a postage meter machine impression) that is readily identifiable, without further action, as having been supplied or affixed on the date of mailing by an employee of the U.S. Postal Service.

2. Withdrawal of Applications

Applications may be withdrawn by written notice or telegram (including mail gram) received at any time before an award is made. Applications may be withdrawn in person by the applicant or by an authorized representative thereof, if the representative's identity is made known and the representative signs a receipt of the proposal.

3. Hand-Delivered Proposals

It is preferred that applications be mailed at least five days prior to the closing date. To be considered for funding, hand-delivered applications must be received by 4:45 p.m., ET, at the specified address. Failure to adhere to the above instructions will be basis for a determination of non-responsiveness. Overnight express mail from carriers other than the U.S. Postal Service will be considered hand-delivered applications and must be received by the above specified date and time.

Part II. Authority

Omnibus Appropriations Resolution, 2003, Public Law 108–7; Consolidated Appropriations Act, 2001, Public Law 106–554, 29 U.S.C. 557b.

Part III. Background

In *Olmstead* v. *L.C.,* 527 U.S. 581, 119 S.Ct. 2176 (1999) (the ''*Olmstead* decision''), the Supreme Court construed Title II of the Americans with Disabilities Act (ADA) to require states to place qualified individuals with mental disabilities in community settings, rather than in institutions, whenever treatment professionals determine that such placement is appropriate, the affected persons do not oppose such placement, and the state can reasonably accommodate the placement, taking into account the resources available to the state and the

needs of others with disabilities. The Department of Justice regulations implementing Title II of the ADA require public entities to administer their services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities. *See* 28 CFR 35.130(d).

In *Olmstead*, the Supreme Court stated that institutional placements of people with disabilities who can live in, and benefit from, community settings perpetuates the unwarranted assumptions that persons so isolated are incapable or unworthy of participating in community life. The Supreme Court stated that ''recognition that unjustified institutional isolation of persons with disabilities is a form of discrimination reflect[ed] two evident judgements'': (1) ''Institutional placements of people with disabilities who can live in, and benefit from, community settings perpetuates the unwarranted assumptions that persons so isolated are incapable or unworthy of participating in community life''; and (2) ''confinement in an institution severely diminishes everyday life activities of individuals, including family relations, social contacts, *work options, economic independence*, educational advancement, and cultural enrichment.'' *Olmstead*, 119 S.Ct. 2176, 2179, 2187 [emphasis added]. This decision affects not only all persons in institutions and segregated settings, but also people with disabilities who are at risk of institutionalization, including people with disabilities on waiting lists to receive community based services and supports.

The Court indicated that one way states can show they are meeting their obligations under the ADA and the *Olmstead* decision is to develop a ''comprehensive, effectively working plan for placing qualified people with mental disabilities in less restrictive settings.'' *Olmstead* at 2179. Based on this, almost all states are in the process of developing, or have already developed such plans.

In support of these state efforts, President George W. Bush issued Executive Order 13217: Community-Based Alternatives for Individuals with Disabilities (the *Olmstead* Executive Order) on June 18, 2001, in which he extended application of the Supreme Court's *Olmstead* decision to all Americans with disabilities, and called upon selected Federal agencies, including the U.S. Department of Labor, to help support governors in their implementation of the *Olmstead* decision. In support of these state efforts and in response to the direction set forth in Executive Order 13217, the ODEP is issuing this SGA for WorkFORCE Action Grants.

In March 2002, the U.S. Secretary of Health and Human Services, Tommy G. Thompson, submitted a report to President Bush, titled Delivering on the Promise, on behalf of the Departments of Labor (DOL), Justice (DOJ), Education (ED), Health and Human Services (HHS), Housing and Urban Development (HUD), Transportation (DOT), Veterans Affairs (VA), the Social Security Administration (SSA) and the Office of Personnel Management (OPM). This report detailed actions being planned by the aforementioned agencies to eliminate barriers and promote community integration. See *http://www.hhs.gov/newfreedom/final.* In this report, the DOL and other Federal agencies noted that successful *Olmstead* planning and implementation efforts must include competitive employment and employment-related supports. Delivering on the Promise identifies several key concerns related to employment that must be addressed, including:

- Fragmentation of existing employment services;
- Isolation and segregation of people with disabilities from ''mainstream'' or generic employment programs and services;
- Lack of access to health insurance;
- The complexity of existing work incentives that are meant to encourage and/or support work efforts;
- Lack of control and choice in selecting employment training and service providers;
- Inadequate work opportunities resulting from attitudinal barriers based on historical and erroneous stereotypes; and
- Lack of accurate data on employment of people with disabilities needed to measure progress in eliminating barriers to their employment.

Many strategies exist for creating and expanding competitive employment opportunities in the community, including those for individuals who have been segregated in institutions, nursing homes, sheltered workshops and day activity programs. Many promising strategies have emerged through decades of research and demonstration projects, and through other public and private activities promoting increased choice and self-determination for people with disabilities. These include multiple ''customized'' employment approaches such as supported employment and supported entrepreneurship; individualized job development; job carving and restructuring; use of personal agents (including individuals with disabilities and family members); development of micro-boards, micro-enterprises, cooperatives and small businesses; and the use of personal budgets and other forms of individualized funding that provide choice and control to the person and promote self-determination.

Accordingly, last year the ODEP awarded 12 WorkFORCE Coordinating Grants, totaling $1,599,910 and three WorkFORCE Action Grants, totaling $1,983,067. This initiative represented the ODEP's support for increasing and improving employment opportunities for the population covered by the *Olmstead* decision, and is demonstrating that such individuals can successfully achieve employment and participate in community life.

The additional WorkFORCE Action Grants represented by this SGA are meant to build on the ODEP's existing WorkFORCE Grant Initiative. Expanding the number of projects funded under the WorkFORCE Grant Initiative will enhance the development of information that can inform the policy development activities of the ODEP, and provide an opportunity for implementation of projects designed under the WorkFORCE Coordinating Grants awarded by the ODEP last year. Additionally, these grants support the President's New Freedom Initiative. The New Freedom Initiative is designed to increase the number of people with disabilities who enter, re-enter, and remain in the workforce. By emphasizing the need to increase the capacity of federally-supported employment and training programs to serve people with significant disabilities, including those covered by the *Olmstead* decision and Executive Order, the current SGA will further the New Freedom Initiative's goals of increased integration of Americans with disabilities into the workforce.

The grants awarded under this SGA will also complement other Federal and state initiatives already underway to make working and living in the community a reality for more people with disabilities, including the state planning and implementation efforts under the U.S. Supreme Court's *Olmstead* decision; the *Olmstead* Executive Order; the Department of Health and Human Services Systems Change Grants; the ODEP Work Incentive, Customized Employment, and Technical Assistance and Training to Providers initiatives; and other related grant opportunities and efforts by the DOL, the HHS, and the SSA under the Workforce Investment Act

(WIA) and the Ticket to Work and Work Incentives Improvement Act (TWWIIA). The WorkFORCE grants will utilize the resources and incentives of these and other initiatives to create competitive employment opportunities for individuals eligible under the *Olmstead* decision and the Executive Order. The resulting employment opportunities for people with disabilities eligible for these programs are essential to accomplish the goal of full integration within the community.

In addition, these grants will support implementation of coordinated workforce development envisioned under the WIA. The WIA established comprehensive reform of existing Federal job training programs, consolidating multiple programs into a unified system and bringing multiple Federal programs together as required partners in the One-Stop delivery system established under the WIA. The One-Stop Centers, which comprise the heart of this system, are in a position to expand employment opportunities for people with disabilities by helping to ensure that the workforce system is accessible both physically and programmatically. To accomplish this, however, additional state and local organizations must be involved, including community based providers of customized employment services. Additional partners necessary to the success of this endeavor for people with disabilities include, but are not limited to, the following: State programs for individuals with cognitive and developmental disabilities; Medicaid; mental health and substance abuse agencies and organizations; transportation and assistive technology providers; Small Business Development Centers; secondary education programs; community colleges; University Centers for Excellence in Developmental Disabilities; foundations; and faith-based and community organizations.

In particular, it is essential that One-Stop Centers have available a variety of eligible training providers in their respective communities to meet the needs of individuals seeking employment. This includes faith-based and community organizations with expertise in customized employment strategies for assisting people with disabilities to achieve choice-based employment. Such innovative partnerships with the One-Stop system hold the promise of dramatically increasing both employment and wages for people with disabilities, in part by increasing their choices for integrated, competitive employment, business ownership, entrepreneurship, and other customized employment options.

In response to these considerations and in view of the potential resources described above, the ODEP will continue its Working for Freedom, Opportunity and Real Choice through Community Employment (WorkFORCE) Grant Initiative by awarding WorkFORCE Action Grants that develop and/or expand the capacity of communities to provide individually determined, customized employment, in partnership with the workforce development system.

Part IV. Funding Availability and Period of Performance

The ODEP anticipates awarding up to 6 grants, ranging from approximately $400,000 to $625,000 per year, totaling $2.5 million, to develop demonstration programs to support the development and coordination of customized community employment opportunities in non-stereotypical jobs for people with disabilities who want to: (1) Move from nursing homes, residential facilities, or other segregated environments into the community; (2) continue living in the community; (3) achieve economic self-sufficiency; and (4) attain full access to, and participation in, their communities. This grant initiative is founded in the belief that to fully participate in community life, such individuals must have the opportunity for employment.

These demonstration grants will be awarded for one year, with four additional option years possible, depending upon the availability of funds and the efficacy of grant activities, established by independent reviews conducted by the ODEP or its designees. It is envisioned that if funding continues for the full five years, the funding for years four and five will be at successively lower rates with funding during year four at 80 percent of the third year funds, and funding during year five at 60 percent of the third year funds. Grantees are expected to use this grant to leverage and develop other public and private resources to ensure sustainability.

Part V. Eligible Applicants and Required Partnerships

Eligible Applicants

Eligible applicants for these demonstration grants are non-profit organizations including faith-based and community organizations (although not 501(c)(4) entities subject to the Lobbying Disclosure Act). To be determined eligible, applicants must:

1. Successful applicants must indicate their intent to register as eligible training providers in their states and coordinate with their local One-Stop Career Center(s);

2. In addition, successful applicants will not utilize certificates authorized under section 14(c) of the Fair Labor Standards Act in their implementation of project activities and will utilize only individually determined customized employment strategies in securing employment for the target population.

Required Partnerships

The purpose of the WorkFORCE Action Grants is to demonstrate the employment potential of people with disabilities through techniques for accomplishing community employment in non-stereotypical integrated settings, utilizing customized employment strategies. These efforts must include the involvement of many key partners, especially those with direct involvement in their area's One-Stop Career Centers.

The target populations to be served are people with disabilities who are either unemployed or under-employed and who are:

- In non-work (*i.e.*, day activity, social clubs), segregated work, or transitioning to work settings; or,
- Expected to be or are determined to be covered under the *Olmstead* decision and Executive Order and therefore part of the state overall *Olmstead* planning and implementation process; or,
- Awaiting employment services and supports following a move from a residential facility, or as part of a plan to move into a community under the Supreme Court's decision in *Olmstead* and the *Olmstead* Executive Order.

In addition, this program is subject to the provisions of the ''Jobs for Veterans Act,'' Public Law 107–288, which provides priority of service to veterans and certain of their spouses in all Department of Labor-funded job training programs. Please note that, to obtain priority of service, a veteran must meet that program's eligibility requirements. Comprehensive policy guidance is being developed and will be issued in the near future.

The target groups to be served by these grants are intended to be those persons with disabilities who are both defined above and who have been among the hardest to serve due to low expectations for employment, lack of employment skills, limited independent living experiences or other individualized needs and supports.

Applicants must:

1. Submit a letter signed by their state's governor, or his or her designee for overall *Olmstead* implementation, that the proposed grant activities will be regarded as an official demonstration

program playing a vital role in the state's *Olmstead* employment implementation effort(s). Moreover, this letter must describe how the lessons learned under implementation of the WorkFORCE Action Grant will be utilized to benefit other communities throughout the state, and thereby provide expanded customized community employment options for people who are covered under the *Olmstead* decision and Executive Order.

2. Grant applications must include evidence of current collaboration and partnerships with a wide variety of state agencies, entities and individuals. Some of the agencies and organizations that should be considered for inclusion are:

- Employment and training agencies;
- State and local Workforce Investment Boards and their One-Stop Career Centers;
- State agencies for substance abuse, vocational rehabilitation, education, Medicaid, mental retardation, mental health, public health, and Temporary Assistance for Needy Families (TANF);
- State Developmental Disability Councils and University Centers for Excellence in Developmental Disabilities;
- Small Business Development Centers,
- Independent Living programs;
- Community colleges, benefits counseling and assistance programs;
- Lending and financial institutions, whose expertise, services, or funds could contribute to employment services and supports needed to secure competitive, customized community employment outcomes for the target group;
- Faith-based and community organizations;
- Community rehabilitation providers;
- Family members, consumers, employers, and any other key agencies or constituencies needed to offer a comprehensive service delivery model.

Part VI. Format Requirements for Grant Application

General Requirements

Applicants must submit one (1) paper copy with an original signature and two (2) additional paper copies of their signed proposal. To aid with the review of applications, USDOL also encourages Applicants to submit an electronic copy of their proposal on a disc or CD using Microsoft Word. Applicants who do not provide an electronic copy will not be penalized. The Application Narrative must be double-spaced with standard one-inch margins (top, bottom, and sides) on 8½ x 11 papers, and be presented on single-sided, numbered pages with the exception of format requirements for the Executive Summary. The Executive Summary must be limited to no more than two single-spaced, single-sided pages on 8½ x 11 papers with standard one-inch margins (top, bottom, and sides) throughout. A font size of at least twelve (12) pitch is required throughout. Applications that fail to meet these requirements will be considered non-responsive.

The three required sections of the application are:

Section I—Project Financial Plan
Section II—Executive Summary—Project Synopsis
Section III—Project Narrative (including Attachments, not to exceed seventy-five (75) pages)

Mandatory requirements for each section are provided as follows in this application package. Applications that fail to meet the stated mandatory requirements of each section will be considered non-responsive.

Mandatory Application Requirements

- Section I. Project Financial Plan (Budget) [The Project Financial Plan will not count against the application page limits.] Section I of the application must include the following three required parts:

(1) Completed ''SF 424—Application for Federal Assistance'' (*See* Appendix A of this SGA for required form.)

(2) Completed ''SF 424A—Budget Information Form'' by line item for all costs required to implement the project design effectively. (*See* Appendix B of this SGA for required forms.)

(3) Budget Narrative and Justification that provides sufficient information to support the reasonableness of the costs included in the budget in relation to the service strategy and planned outcomes.

The application must include one SF–424 with the original signatures of the legal entity applying for grant funding and two additional copies. Applicants shall indicate on the SF–424 the organization's IRS status, if applicable. Under the Lobbying Disclosure Act of 1995, section 18 (29 U.S.C. 1611), an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities will not be eligible for the receipt of Federal funds constituting an award, grant, or loan. (See 2 U.S.C. 1611; 26 U.S.C. 501(c)(4).) For item 10 of the SF–424, the Catalog of Federal Domestic Assistance (CFDA) number for the program is 17.720.

The Budget Narrative and Justification must describe all costs associated with implementing the project that are to be covered with grant funds. Grantees must support the travel and associated costs with sending at least one representative to the annual ODEP Policy Conference for Grantees, to be held in Washington, DC, at a time and place to be determined. Grantees must comply with the ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments,'' (also known as the ''Common Rule'') codified at 29 CFR part 97, and ''Grants and Agreements with Institutes of Higher Education, Hospitals, and Other Non-Profit Organizations (also known as OMB Circular A–110), codified at 29 CFR part 95 and must comply with the applicable OMB cost principles circulars, as identified in 29 CFR 95.27 and 29 CFR 97.22(b).

Grantees may use funds in a flexible manner, as determined appropriate by input from stakeholders and identified needs, so long as requirements for outcome and evaluation data and other requirements of Federal statutes, regulations, administrative requirements, and OMB circulars and the requirements delineated in this SGA are met.

In addition, the budget must include on a separate page a detailed cost analysis of each line item. Justification for administrative costs must be provided. Approval of a budget by the DOL is not the same as the approval of actual costs. The individual signing the SF–424 on behalf of the applicant must represent and be able to legally bind the responsible financial and administrative entity for a grant should that application result in an award. The applicant must also include the Assurances and Certifications Signature Page (Appendix C).

- Section II. Executive Summary—Project Synopsis (The Executive Summary is limited to no more than two single-spaced, single-sided pages on 8½ x 11 paper with standard margins throughout). Each application shall include a project synopsis that identifies the following:
- The applicant;
- The amount of funds requested;
- The planned period of performance;
- The list of partners, as appropriate;
- An overview of how the applicant will identify the population to be served (including the estimated number and types of disability), the environments such individuals are currently experiencing (such as institutions, nursing homes, segregated day programs, etc.), and methods that will be used to promote community employment, including customized

employment strategies listed in this SGA; and

- An overview of the plan for sustainability once Federal funding ceases.
- Section III. Project Narrative (The Project Narrative plus attachments are limited to no more than seventy-five (75), 8½ x 11 pages, double-spaced with standard one-inch margins (top, bottom, and sides), and must be presented on single-sided, numbered pages. **Note:** The Financial Plan, the Executive Summary, and the Appendices are not included in the seventy-five (75)-page limit.) The requirements for the project narrative are described below under Part VII—Statement of Work.

All text in the application narrative, including titles, headings, footnotes, quotations, and captions, as well as all text in charts, tables, figures, and graphs must be double-spaced (no more than three lines per vertical inch); and, if using a proportional computer font, use no smaller than a 12-point font, and an average character density no greater than 18 characters per inch (if using a non-proportional font or a typewriter, do not use more than 12 characters per inch). Applications that fail to meet these requirements will be considered non-responsive.

Part VII. Government Requirements/ Statement of Work [Project Narrative]

The purpose of the WorkFORCE Action Grants is to demonstrate the employment potential of people with disabilities through techniques for accomplishing community employment in non-stereotypical integrated settings, utilizing customized employment strategies. These efforts must include the involvement of many key partners, especially those with direct involvement in their area's One-Stop Career Centers, as described in Section V above.

For purposes of this solicitation, customized employment means individualizing the employment relationship between employees and employers in ways that meet the needs of both. It is based on an individualized determination of the strengths, needs, and interests of the person with a disability, and is also designed to meet the specific needs of the employer. It may include approaches such as supported employment; supported entrepreneurship; individualized job development; job carving and restructuring; use of personal agents (including individuals with disabilities and family members); development of micro-boards, micro-enterprises, cooperatives and small businesses; and use of personal budgets and other forms of individualized funding that provide choice and control to the person and promote self-determination. These and other job development or restructuring strategies result in job responsibilities being customized and individually negotiated to fit the needs of individuals with disabilities. Customized employment assumes the provision of reasonable accommodations and supports necessary for the individual to perform the functions of a job that is individually negotiated and developed.

Each applicant for these grants shall describe its plan for expanding capacity for, and provision of, customized employment opportunities to the target groups as defined in Part V above.

The Project Narrative, or Section III of the grant application, should provide complete information on how the applicant will address the following DOL priorities for fiscal year 2003:

(1) Increase the availability of skill training, employment opportunities and career advancement for persons with disabilities; and

(2) Develop comprehensive One-Stop Centers, which are welcoming and are valued providers of choice by customers with disabilities seeking workforce assistance by assuring the availability of staff trained on disability issues, personalized employment counseling, knowledgeable support that addresses employment barriers and work incentives, and the availability of accommodations and technologies for diverse disabilities.

Proposals will be rated based upon the quality of the applicant's response in addressing the four criteria described below in terms of a comprehensive strategic approach that addresses the ODEP's priorities noted above. The four criteria (Statement of Need/National Significance, Comprehensive Service Strategy, Sustainability, and Management Plan and Outcomes) MUST be addressed and the applicant's accomplishments or status with regard to each item provided.

The ODEP, however, does not expect the applicant to fully incorporate every item listed as part of their strategy and proposal design. The ODEP recognizes that the needs and requirements of each state and community may be different, and therefore, some of the options identified may be more relevant than others in a particular state.

1. Statement of Need/Significance of the Project (15 Points)

The purpose of the Statement of Need criteria is to establish the overall status of disability issues relevant to the targeted population in the applicant's state; to identify strengths and deficiencies to be addressed by the applicant's proposal; to identify the overall scope of the proposal's objectives and design; to present the applicant's need for the grant resources; to demonstrate significance of the proposed project; and to demonstrate the current and proposed partnerships and collaborative efforts to develop or demonstrate promising new strategies, practices, and/or innovations. The narrative in this section should include:

(1) The potential contribution of the proposed project to increase knowledge or understanding of problems, issues, or effective strategies for community-based organizations and other potential partners to use customized employment strategies to increase employment, choice and wages, and influence systems change for the *Olmstead* covered population.

(2) The extent to which the applicant demonstrates an understanding of the issues the state and proposed geographic area are currently facing in their overall *Olmstead* implementation efforts;

(3) The extent to which the applicant demonstrates a clear understanding of customizing employment and the range of strategies it can incorporate;

(4) The extent to which the proposed project is likely to yield findings that may be used by other appropriate agencies and organizations;

(5) The extent to which the proposed project involves the development or demonstration of promising new strategies that build upon, or are alternatives to, existing strategies;

(6) The extent to which the promising practices of the proposed project will be disseminated in ways that will enable others to use the information or strategies;

(7) The potential replicability (national significance) of the proposed project or strategies, including, as appropriate, the potential for implementation in a variety of settings; and

(8) The importance or magnitude of the results, which are likely to be attained by the proposed project.

In evaluating the quality of the proposal narrative, the ODEP will consider the applicant's identified needs and proposed approaches to addressing the needs in the context of the ODEP's priorities.

2. Comprehensive Service Strategy (30 Points)

The purpose of the Comprehensive Service Strategy criteria is to identify the approach proposed by the grantee to implement the WorkFORCE Action Grant. In general, this requires extensive

linkages and on-site knowledge of applicable resources that address multiple disability issues and barriers to community integration and employment that are commonly experienced by the *Olmstead* covered population.

A. Staff Capacity—the applicant must:

(1) Describe the proposed staffing of the project. Identify how it will ensure that trained staff with adequate knowledge of diverse disabilities, knowledge of diverse customized employment strategies, and employment-related experience for the target population will be available to provide grant related services.

(2) Summarize the qualifications, including relevant education, training and experience of key project personnel, as well as project consultants or subcontractors, including their qualifications, relevant training and experience. Attach copies of resumes in the Appendices.

(3) Describe the applicant's experience in serving people with disabilities and in providing customized employment services.

(4) Describe the extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

B. Proposed Project Design and its Evaluation—the application must address the proposed design for the WorkFORCE Action Grant, including its response to the requirements outlined in Part V (Eligible Applicants and Required Partnerships) of this Solicitation.

The Project Design must:

(1) Address the movement of individuals from segregated settings to customized employment opportunities in the community;

(2) Work in coordination with their state's *Olmstead* lead agency on their state's overall *Olmstead* plan, and describe how they will contribute to the development of their state's plan and implementation strategy related to employment;

(3) Integrate customized employment strategies with their state's employment programs and services, including existing services available through the One-Stop Centers, the state and local Workforce Investment Boards, and their partners;

(4) Coordinate their efforts with existing *Olmstead* activities and programs including grant activities and initiatives funded by the SSA, the Centers for Medicaid and Medicare Services at HHS, and grant activities and initiatives funded by the Center for Mental Health Services of HHS;

(5) Develop customized employment opportunities in a variety of occupations and industries based on the strengths, needs, and desires of the individual with a disability, including self-employment and entrepreneurship where appropriate. Services and supports must be organized in ways that provide informed choice and promote self-determination;

(6) Establish employer involvement; track and respond to customer service and satisfaction for both persons with disabilities and employers; and provide services, including follow-up services, to ensure job retention and career development;

(7) Collaborate with other faith-based and community organizations in their state in order to expand opportunities for customized employment for the target group. This includes facilitating the availability and use of customized employment strategies by such organizations, as well as facilitating such organizations registering as eligible training providers with their local One-Stop Career Centers;

(8) Educate relevant stakeholders and systems personnel about changes needed to increase customized community employment outcomes for individuals with disabilities;

(9) Consider the usefulness of increasing the availability of personal agents and job development personnel offering customized services through customer-controlled approaches that result in customized employment. One possible area of focus could include demonstrating the effectiveness of paying family members or other individuals with disabilities to serve as personal agents when selected by the individual with a disability to assist in negotiating and implementing employment plans and services;

(10) Incorporate use of funds leveraged across several systems available to people with disabilities through personal budgets and other forms of self-directed accounts.

In evaluating the quality of the proposed project design, ODEP will also consider the following factors:

(a) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable;

(b) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population and other identified needs and the quality of the applicant's plans for recruiting and retaining the target population;

(c) The extent to which the design of the proposed project provides procedures and approaches for collaboration and coordination with key agencies and organizations and identification of critical roles;

(d) The extent to which the design of the proposed project provides clear understanding of and experience with utilization of customized employment strategies for increasing employment, choice and earnings of individuals with significant disabilities;

(e) The extent to which the proposed project will be coordinated, including demonstrated support from the state governor or designated *Olmstead* agency and commitment from key organizations, employers, and agencies;

(f) The extent to which the applicant encourages involvement of people with disabilities and their families, experts and organizations, and other relevant stakeholders in project activities;

(g) The extent to which the design of the project will facilitate an increase in the number of faith-based and community organizations that register as eligible training providers or as providers of supplemental and supportive services with their local One-Stop Center;

(h) The extent to which performance feedback and continuous improvement are integral to the design of the proposed project;

(i) The extent to which the management plan for project implementation is likely to achieve the objectives of the proposed project on time and within budget; and

(j) The extent to which the proposed project design features innovative strategies to implement customized employment and choice.

Letters of Commitment. Applicants can include letters of support if they provide specific commitments. Such letters can increase an applicant's score by showing that the commitments in the text of the proposal are serious. Form letters will not be considered. *See also* Part V.

3. Sustainability (25 Points)

The purpose of the sustainability criteria is to identify strategies for ensuring that activities funded under the grant will continue once federal funding ceases. Sustainability objectives must be built into the project design and ongoing project operation. Applicants must:

(1) Identify resources and partnerships that are an integral element of the project. Projects funded under this SGA must leverage a combination of Federal, state, and local public sector resources, as well as local non-profit sector resources for purposes of sustainability. Accordingly, in this section the applicant should enumerate

these resources, describe any specific existing contractual commitments, and provide concrete evidence of sustainability;

(2) Identify activities and in-kind elements of sustained support. ODEP considers detailed commitments for specific new activities as more important than promises of in-kind supports in showing sustained support for the project. Grants recently received from another agency can be discussed in the proposal, but the applicant should be precise about which activities preceded this grant and which will occur because of the grant;

(3) Detail how Federal, state, and local public sector commitments contribute to the sustainability of this project following completion of the grant. Examples of such commitments could include: commitment from state vocational rehabilitation, one-stop center, state developmental disability, state Medicaid, or state general revenue funding to support expanded customized employment services for individuals securing employment through the agency; status as Employment Network under the Ticket to Work and Work Incentive Improvement Act providing customized employment services to eligible ticket-holders; private sector funding through foundations, financial or lending agencies, or other relevant collaborative arrangements for continuing provision or expansion of customized employment services in the community.

In evaluating the quality of the plan for sustainability, ODEP will also consider the following factors to be of particular importance:

(a) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the grant period, including the quality of the applicant's plans for implementing the project's activities in years four and five when Federal funding will be reduced.

(b) The likelihood of the applicant successfully securing state ownership and participation in these projects when the grant funds cease.

(c) The extent to which partnerships with outside entities (including public and private disability and faith-based and community organizations) and funding from additional Federal, state, and local resources will be effectively leveraged and utilized in continuing the WorkFORCE Action activities after the expiration of this grant. *See* Part V.

4. Management and Outcomes (30 Points)

The purpose of the Management and Outcomes criteria is to determine whether the applicant has developed an adequate management plan to effectively carry out the objectives and scope of the proposed project on time and within budget, to describe the predicted outcomes resulting from activities funded under this SGA, and to identify the ''methods of evaluation'' that will be used by the grantee to determine success.

Applicants should provide a detailed management plan, which identifies the critical activities, time frames, and responsibilities for effectively implementing the project, including the evaluation process for assuring successful implementation of grant objectives.

In addition, applicants should outline the strategy for documenting and reporting the activities undertaken during the life of the grant for the ODEP's future use in working with other grantees and constituencies.

In evaluating the management and outcomes criteria, the ODEP considers the following factors to be of particular importance:

(a) The extent to which the proposed budget and narrative justifications are adequate to support the proposed project;

(b) The extent to which performance feedback and continuous improvement are integral to the design of the proposed project;

(c) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies;

(d) The extent to which the evaluation will provide information to other programs about effective strategies suitable for replication or testing in other settings;

(e) The extent to which the methods of evaluation include the objective use of performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data;

(f) The extent to which the methods of evaluation measure in both quantitative and qualitative terms, program results and satisfaction of customers, both people with disabilities and employers;

(g) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project;

(h) The extent to which the principal investigator and other key personnel are appropriate and adequate to meet the objectives of the proposed projects;

(i) The extent to which the budget is adequate to support and sustain the proposed project activities over the projected five-year period.

(j) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

Part VIII. Monitoring and Reporting

Monitoring

The ODEP is responsible for ensuring the effective implementation of each competitive grant project in accordance with the provisions of this announcement and the terms of the grant award document.

Applicants should assume that ODEP staff, or their designees, will conduct on-site project reviews periodically. Reviews will focus on timely project implementation, performance in meeting the grant's programmatic goals and objectives, expenditures of grant funds on allowable activities, integration and coordination with other resources and service providers in the local area, project management and administration of project activities. WorkFORCE Action Grants may be subject to other additional reviews at the discretion of the ODEP.

Reporting

Grantees will be required to submit quarterly financial and narrative progress reports. In addition, all grantees will be expected to provide information on individuals with disabilities securing employment through use of customized strategies (including information on types of jobs, wages, and benefits secured by specific individuals with disabilities) and other areas addressed through the linkages and networks facilitated by project activities.

Grantees will be required to submit periodic financial and participation reports. Specifically the following reports will be required:

A. Quarterly reports: The quarterly report is estimated to take ten hours to complete. The form for the Quarterly Report will be provided by the ODEP. The ODEP will work with the grantee to help refine the requirements of the report, which will, among other things, include measures of ongoing analysis for continuous improvement and customer satisfaction.

B. Standard Form 269; Financial Status Report Form (FSR) will be completed on a quarterly basis, using the on-line electronic reporting system.

C. Final Project Report: The final report will include an assessment of project performance and outcomes achieved. The final report is estimated to take 20 hours. This report will be submitted in hard copy and on electronic disk using a format and

following instructions, which will be provided by the DOL. A draft of the final report is due to the ODEP 45 days before the termination of the grant. The final report is due to the DOL 60 days following the termination of the grant.

All grantees must agree to cooperate with an independent evaluation to be conducted by the ODEP. The ODEP will arrange for and conduct this independent evaluation of the outcomes, impacts, and accomplishments of each funded project. Grantees must agree to make available records on all parts of project activity, including participant employment and wage data, and to provide access to personnel, as specified by the evaluator(s), under the direction of the ODEP. This independent evaluation is separate from the ongoing evaluation for continuous improvement required of the grantee for project implementation. The ODEP's evaluation of the WorkFORCE Action Grants includes a process evaluation that includes extensive information pertaining to achievements under the grant, summary information, number of people with disabilities receiving services, number of people employed through the One-Stop system and other sources.

Grantees must also agree to work with the ODEP in its various technical assistance efforts in order to freely share with others what is learned about delivering customized employment services to the *Olmstead* population. Grantees must agree to collaborate with other research institutes, centers, studies, and evaluations that are supported by the DOL and other relevant Federal agencies, as appropriate. Finally, Grantees must agree to actively utilize the programs sponsored by the ODEP, including the Job Accommodation Network, (*http://www.jan.wvu.edu*), and the Employer Assistance Referral Network (*http://www.earnworks.com*).

Part IX. Review Process and Evaluation Criteria

All applications will be reviewed for compliance with the requirements of this notice. A careful evaluation of applications will be made by a technical review panel, which will evaluate the applications against the rating criteria listed in this SGA. The panel results are advisory in nature and not binding on the Grant Officer. The ODEP may elect to award grants with or without discussion with the offeror. In situations without discussions, an award will be based on the offeror's signature on the SF–424, which constitutes a binding offer. The Grant Officer may consider any information that is available and will make final award decisions based on what is most advantageous to the Government, considering such factors as:

- Panel findings;
- Geographic distribution of the competitive applications and based on location of the existing *Olmstead* WorkFORCE Action Grants (Boston, MA; Peoria, IL; and, Decatur, GA) and;
- Assuring a variety of program designs; and
- Availability of funds

X. Administration Provisions

A. Administrative Standards and Provisions

Grantees are strongly encouraged to read these regulations before submitting a proposal. The grant awarded under this SGA shall be subject to the following as applicable:

- 29 CFR part 95—Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, and With Commercial Organizations, Foreign Governments, Organizations Under the Jurisdiction of Foreign Governments, and International Organizations;
- 29 CFR part 96— Audit Requirements for Grants, Contracts, and Other Agreements.
- 29 CFR part 97—Uniform Administrative Requirement for Grants and Cooperative Agreements to State and Local Governments.

B. Allowable Cost

Determinations of allowable costs shall be made in accordance with the following applicable Federal cost principles:

- State and Local Government—OMB Circular A–87
- Nonprofit Organizations—OMB Circular A–122
- Profit-Making Commercial Firms—48 CFR part 31

Profit will not be considered an allowable cost in any case.

C. Grant Assurances

As a condition of the award, the applicant must certify that it will comply fully with the nondiscrimination and equal opportunity provisions of the following laws:

- 29 CFR Part 31—Nondiscrimination in Federally-assisted programs of the Department of Labor, effectuation of Title VI of the Civil Rights Act of 1964.
- 29 CFR Part 32—Nondiscrimination on the Basis of Disability in Programs and Activities Receiving or Benefiting from Federal Assistance. (Implementing section 504 of the Rehabilitation Act, 29 U.S.C. 794)
- 29 CFR Part 36—Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance. (Implementing title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.*)
- 29 CFR Part 37—Nondiscrimination and Equal Opportunity Provisions of the Workforce Investment Act of 1998 (WIA), (Implementing Section 188 of the Workforce Investment Act, 29 U.S.C. 2938)

The applicant must include assurances and certifications that it will comply with these laws in its grant application. The assurances and certifications are attached as Appendix C.

Signed at Washington, DC, this 20th day of May, 2003

Lawrence J. Kuss,

Grant Officer.

Appendix A. Application for Federal Assistance, Form SF–424

Appendix B. Budget Information Sheet, Form SF–424A

Appendix C. Assurances and Certifications Signature Page

Appendix D. Survey on Ensuring Equal Opportunity

BILLING CODE 4510–CX–P

APPLICATION FOR FEDERAL ASSISTANCE

OMB Approval No. 0348-0043

2. DATE SUBMITTED	Applicant Identifier	
3. DATE RECEIVED BY STATE	State Application Identifier	
4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier	

1. TYPE OF SUBMISSION:

Application
- ☐ **Construction**
- ☐ **Non-Construction**

Preapplication
- ☐ **Construction**
- ☐ **Non-Construction**

5. APPLICANT INFORMATION

Legal Name:

Organizational Unit:

Address *(give city, county, State, and zip code):*

Name and telephone number of person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER *(EIN):*

☐☐ — ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify) _____

8. TYPE OF APPLICATION:

☐ **New** ☐ **Continuation** ☐ **Revision**

If Revision, enter appropriate letter(s) in box(es) ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other*(specify):*

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

☐☐ — ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(Cities, Counties, States, etc.):*

13. PROPOSED PROJECT		**14. CONGRESSIONAL DISTRICTS OF:**	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:

a. Federal	$ .00
b. Applicant	$ .00
c. State	$ .00
d. Local	$ .00
e. Other	$ .00
f. Program Income	$ .00
g. TOTAL	$ 0.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. No. ☐ PROGRAM IS NOT COVERED BY E. O. 12372
☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ **Yes** **If "Yes," attach an explanation.** ☐ **No**

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.

a. Type Name of Authorized Representative	b. Title	c. Telephone Number
d. Signature of Authorized Representative		e. Date Signed

Previous Edition Usable
Authorized for Local Reproduction

Standard Form 424 (Rev. 7-97)
Prescribed by OMB Circular A-102

Appendix A

INSTRUCTIONS FOR THE SF-424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0043), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:
1.	Self-explanatory.
2.	Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).
3.	State use only (if applicable).
4.	If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5.	Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7.	Enter the appropriate letter in the space provided.
8.	Check appropriate box and enter appropriate letter(s) in the space(s) provided: -- "New" means a new assistance award. -- "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date. -- "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9.	Name of Federal agency from which assistance is being requested with this application.
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12.	List only the largest political entities affected (e.g., State, counties, cities).
13.	Self-explanatory.
14.	List the applicant's Congressional District and any District(s) affected by the program or project.
15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BUDGET INFORMATION - Non-Construction Programs

OMB Approval No. 0348-0044

SECTION A - BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$ 0.00
2.						0.00
3.						0.00
4.						0.00
5. Totals		$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION B - BUDGET CATEGORIES

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total
	(1)	(2)	(3)	(4)	(5)
a. Personnel	$	$	$	$	$ 0.00
b. Fringe Benefits					0.00
c. Travel					0.00
d. Equipment					0.00
e. Supplies					0.00
f. Contractual					0.00
g. Construction					0.00
h. Other					0.00
i. Total Direct Charges *(sum of 6a-6h)*	0.00	0.00	0.00	0.00	0.00
j. Indirect Charges					0.00
k. TOTALS *(sum of 6i and 6j)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
7. Program Income	$	$	$	$	$ 0.00

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Appendix B

SECTION C - NON-FEDERAL RESOURCES				
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$ 0.00
9.				0.00
10.				0.00
11.				0.00
12. TOTAL *(sum of lines 8-11)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$ 0.00	$	$	$	$
14. Non-Federal	0.00				
15. TOTAL *(sum of lines 13 and 14)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT				
(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.				
20. TOTAL *(sum of lines 16-19)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION F - OTHER BUDGET INFORMATION	
21. Direct Charges:	22. Indirect Charges:
23. Remarks:	

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INSTRUCTIONS FOR THE SF-424A

Public reporting burden for this collection of information is estimated to average 180 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0044), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

Section A. Budget Summary Lines 1-4 Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the Catalog program title and the Catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the Catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the Catalog program title on each line in *Column* (a) and the respective Catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1-4, Columns (c) through (g)

For new applications, leave Column (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 - Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Line 6a-i - Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount, Show under the program

INSTRUCTIONS FOR THE SF-424A (continued)

narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal Resources

Lines 8-11 Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a) - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b) - Enter the contribution to be made by the applicant.

Column (c) - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d) - Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e) - Enter totals of Columns (b), (c), and (d).

Line 12 - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13 - Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14 - Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15 - Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16-19 - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20 - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21 - Use this space to explain amounts for individual direct object class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22 - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23 - Provide any other explanations or comments deemed necessary.

OMB Approval No. 0348-0040

ASSURANCES - NON-CONSTRUCTION PROGRAMS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0040), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

NOTE: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant, I certify that the applicant:

1. Has the legal authority to apply for Federal assistance and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project cost) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§4728-4763) relating to prescribed standards for merit systems for programs funded under one of the 19 statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. §§290 dd-3 and 290 ee 3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. §§3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and, (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally-assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply, as applicable, with provisions of the Hatch Act (5 U.S.C. §§1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

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Appendix C

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§276a to 276a-7), the Copeland Act (40 U.S.C. §276c and 18 U.S.C. §874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§327-333), regarding labor standards for federally-assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§1451 et seq.); (f) conformity of Federal actions to State (Clean Air) Implementation Plans under Section 176(c) of the Clean Air Act of 1955, as amended (42 U.S.C. §§7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended (P.L. 93-523); and, (h) protection of endangered species under the Endangered Species Act of 1973, as amended (P.L. 93-205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. §470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. §§469a-1 et seq.).

14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. §§2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§4801 et seq.) which prohibits the use of lead-based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act Amendments of 1996 and OMB Circular No. A-133, "Audits of States, Local Governments, and Non-Profit Organizations."

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

Standard Form 424B (Rev. 7-97) Back

Survey on Ensuring Equal Opportunity

Federal Agency Use Only

OMB No. 1225-0083 Exp. 02/28/2006

NOTE: Please place survey form directly behind the Standard Application for Federal Assistance (SF 424) fact sheet.

Purpose: This form is for applicants that are private nonprofit organizations (not including private universities). Please complete it to assist the federal government in ensuring that all qualified applicants, small or large, non-religious or faith-based, have an equal opportunity to compete for federal funding. Information provided on this form will not be considered in any way in making funding decisions and will not be included in the federal grants database.

1. Does the applicant have 501(c)(3) status?

❑ Yes ❑ No

2. How many full-time equivalent employees does the applicant have? *(Check only one box).*

❑ 3 or Fewer ❑ 15-50
❑ 4-5 ❑ 51-100
❑ 6-14 ❑ over 100

3. What is the size of the applicant's annual budget? *(Check only one box.)*

❑ Less Than $150,000
❑ $150,000 - $299,999
❑ $300,000 - $499,999
❑ $500,000 - $999,999
❑ $1,000,000 - $4,999,999
❑ $5,000,000 or more

4. Is the applicant a faith-based/religious organization?

❑ Yes ❑ No

5. Is the applicant a non-religious community-based organization?

❑ Yes ❑ No

6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?

❑ Yes ❑ No

7. Has the applicant ever received a government grant or contract (Federal, State, or local)?

❑ Yes ❑ No

8. Is the applicant a local affiliate of a national organization?

❑ Yes ❑ No

Appendix D

Survey Instructions on Ensuring Equal Opportunity for Applicants

1. 501(c) (3) statuses is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.

2. For example, two part-time employees who each work half time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.

3. Annual budget means the amount of money your organization spends each year on all of its activities.

4. Self-identify.

5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.

6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.

7. Self-explanatory.

8. Self-explanatory

Paperwork Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 1225-0083. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: Departmental Clearance Officer, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-1301, Washington, D.C. 20210. If you have comments or concerns regarding the status of your individual submission of this form, write directly to: Joyce I. Mays, Application Control Center, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.

[FR Doc. 03–13400 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–CX–C

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–41,288 & NAFTA–6104]

International Truck and Engine Corp., A Subsidiary of Navistar International Corp., Springfield, OH; Notice of Affirmative Determination Regarding Application for Reconsideration

By letter of October 9, 2003, the International Union, United Automobile, Aerospace & Agricultural Workers of America—UAW, Region 2B, and Local Unions 402 and 658 requested administrative reconsideration of the Department's negative determination regarding eligibility for workers and former workers of the subject firm to apply for Trade Adjustment Assistance (TAA) under petition TA–W–41,288 and North American Free Trade Agreement-Transitional Adjustment Assistance (NAFTA–TAA) under petition NAFTA–6104. The denial notices were signed on August 9, 2002, and published in the **Federal Register** on September 10, 2002 (67 FR 57454).

The Department reviewed the request for reconsideration and has determined that the Department will examine the petitioner's allegations claiming that the company may have shifted production to a foreign source and imported products competitive with those produced at the subject facility during the relevant period.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC this 9th day of May, 2003.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13402 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–50,366]

Agere Systems, Inc., Optoelectronics Division, Microelectronics Business, Breingsville, PA; Notice of Affirmative Determination Regarding Application for Reconsideration

By letter of March 24, 2003, the International Brotherhood of Electrical Workers, Local 1560 requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance. The denial notice was signed on January 27, 2003 and published in the **Federal Register** on February 24, 2003 (68 FR 8619).

The Department of Labor has reviewed the request for reconsideration and has determined that based on information provided by the petitioner and review of the initial investigation, further survey of the subject firm's customers will be conducted.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC this 12th day of May 2003.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13403 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–51,269]

Hamilton Beach/Proctor-Silex, Inc.; a Subsidiary of NACCO Industries, Inc., Southern Pines, NC; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on March 21, 2003, in response to a petition filed by a company official on behalf of workers at Hamilton Beach/Proctor-Silex, Inc., a Subsidiary of Nacco Industries, Inc., Southern Pines, North Carolina.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation would serve no purpose and the investigation under this petition has been terminated.

Signed at Washington, DC, this 12th day of May, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13404 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–51,701]

Kelly's Kids, Natchez, MS; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on May 7, 2003 in response to a petition filed by a company official on behalf of workers at Kelly's Kids, Natchez, Mississippi.

The company official has requested that the investigation be terminated.

Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 14th day of May, 2003.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13411 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–51,570]

Lydall Composite Materials, Covington, TN; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on April 23, 2003 in response to a petition filed on behalf of workers at Lydall Composite Materials, Covington, Tennessee. Workers at the subject firm produced composite fiber materials.

The investigation revealed that all workers were separated from the subject firm more than one year before the date of the petition. Section 223(b)(1) of the Act specifies that no certification may apply to any worker whose separation occurred more than one year before the date of the petition. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 12th day of May, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13407 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–51,609]

Manpower International Leased Workers Employed at Motorola, Inc., iDen Subscriber Division, Plantation, FL; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on April 25, 2003 in response to a worker petition filed by a state agency representative on behalf of workers at Manpower International. Leased workers at Motorola, Inc., iDen Subscriber Division, Plantation, Florida is the subject of this investigation.

The petitioning group of workers is covered by an active certification issued on July 23, 2001 which remains in effect (TA–W–39,588). That certification was amended on May 14, 2003 to include the current petitioners. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 14th day of May, 2003.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13409 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–51,563]

OmniGlow Corporation, West Springfield, MA; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on April 22, 2003 in response to a petition filed by a company official on behalf of workers at OmniGlow Corporation, West Springfield, Massachusetts.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 13th day of May, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13406 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–51,580]

Plexus, San Diego, CA; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on February 24, 2003, in response to a worker petition filed on behalf of workers at Plexus, San Diego, California.

The petitioning group of workers is covered by an active certification issued on April 11, 2003 and which remains in effect (TA–W–51,003). Consequently, further investigation in this case would serve no purpose, and the investigation may be terminated.

Signed in Washington, DC, this 12th day of May, 2003.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13408 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–51,498]

Precision Interconnect, a Division of Tyco Healthcare Group, LP, Broomfield, CO; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on April 15, 2003 in response to a worker petition filed by a company official on behalf of workers at Precision Interconnect, a division of Tyco Healthcare Group, LP, Broomfield, Colorado.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 13th day of May, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13405 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–51,690]

Tyson Food, Inc., Berlin, MD; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on May 6, 2003 in response to a worker petition filed by a company official on behalf of workers at Tyson Food, Inc., Berlin, Maryland.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 14th day of May, 2003.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–13410 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment Standards Administration

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment Standards Administration is soliciting comments concerning the proposed collection: Regulations Governing the Administration of the Longshore and Harbor Workers'

Compensation Act (LS–200, LS–201, LS–203, LS–204, LS–262, LS–267, LS–271, LS–513).

A copy of the proposed information collection request can be obtained by contacting the office listed below in the addressee section of this Notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before July 28, 2003.

ADDRESSES: Ms. Hazel M. Bell, U.S. Department of Labor, 200 Constitution Ave., NW., Room S–3201, Washington, DC 20210, telephone (202) 693–0418, fax (202) 693–1451, Email *hbell@fenix2.dol-esa.gov.* Please use only one method of transmission for comments (mail, fax, or Email).

SUPPLEMENTARY INFORMATION:

I. *Background:* The Longshore and Harbor Workers' Compensation Act, as amended (20 CFR 702.162, 702.174, 702.175, 20 CFR 702.242, 20 CFR 702.285, 702.321, 702.201, and 702.111) pertains to the provision of benefits to workers injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel, as well as coverage extended to certain other employees. The Longshore Act administration requirements include: payment of compensation liens incurred by Trust Funds; certification of exemption and reinstatement of employers who are engaged in the building, repairing, or dismantling of exclusively small vessels; settlement of cases under the Act; reporting of earnings by injured claimants receiving benefits under the Act; filing applications for relief under second injury provisions; and, maintenance of injury reports under the Act. This information collection is currently approved for use through November 30, 2003.

II. *Review Focus:* The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

III. *Current Actions:* The Department of Labor (DOL) seeks extension of approval to collect this information in order to carry out its responsibility to insure that Longshore beneficiaries are receiving appropriate benefits.

Failure to request this information, would result in no way to insure beneficiaries are receiving the correct amount of benefits.

Type of Review: Extension.

Agency: Employment Standards Administration.

Title: Regulations Governing the Administration of the Longshore and Harbor Workers' Compensation Act.

OMB Number: 1215–0160.

Agency Number: (LS–200, LS–201, LS–203, LS–204, LS–262, LS–267, LS–271, LS–513).

Affected Public: Individuals or households, Businesses or other for profit, Small businesses or organizations.

Total Respondents: 128,152.

Total Responses: 128,152.

Average Time Per Response for Reporting:

LS–200—10 minutes.

LS–201, 203, 204, 262— 15 minutes.

LS–267—2 minutes.

LS–271—2 hours.

LS–513—30 minutes.

Frequency: On Occassion.

Estimated Total Burden Hours: 63,049.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $56,806.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: May 21, 2003.

Bruce Bohanon,

Chief, Branch of Management Review and Internal Control, Division of Financial Management, Office of Management, Administration and Planning, Employment Standards Administration.

[FR Doc. 03–13401 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–CF–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Finding of Exception Pursuant to Section 501(f) of the Mine Act

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: The Mine Safety and Health Administration (MSHA) is granting an exception to certain mandatory safety standards to the Mathies Mine pursuant to section 501(f) of the Federal Mine Safety and Health Act of 1977 (Mine Act).

DATES: This notice is effective upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ray McKinney, Administrator for Coal Mine Safety and Health, 1100 Wilson Blvd., Room 2424, Arlington, Virginia 22209–3939; phone: 202–693–9502; fax: 202–693–9501; E-mail: *mckinney-ray@msha.gov.*

SUPPLEMENTARY INFORMATION: The Mine Safety and Health Administration (MSHA) is granting to the Mathies Mine in Union Township, Washington County, Pennsylvania an exception to certain mandatory safety standards for the purpose of allowing researchers from Carnegie Mellon University to conduct an experiment by testing a self-propelled, robot device in the mine. This exception is granted pursuant to section 501(f) of the Federal Mine Safety and Health Act of 1977 (Mine Act).

Section 501(f) of the Mine Act states that:

> The Secretary is authorized to grant on a mine-by-mine basis an exception to any mandatory health or safety standard under this Act for the purpose of permitting, under such terms and conditions as he may prescribe, accredited educational institutions the opportunity for experimenting with new and improved techniques and equipment to improve the health and safety of miners. No such exception shall be granted unless the Secretary finds that the granting of the exception will not adversely affect the health and safety of miners and publishes his findings.

The robot device, known as ''Groundhog,'' will conduct an exploratory underground survey of a haulageway through a section of the Mathies Mine which has been unoccupied and in non-producing status for one year. The haulageway consists of two naturally ventilated passages from the storage yard to the preparation plant. Groundhog will start its exploration at the storage yard portal, pass through the entire length of the haulageway, and emerge at the

preparation plant portal. During the course of this experiment, no miners or any other personnel will enter the non-producing mine.

This experiment demonstrates new techniques and equipment which will improve the health and safety of miners by mapping unknown mine areas without endangering miners. Mathies Mine submitted a plan to MSHA which governs all phases of the experiment at the mine. This grant of exceptions to mandatory safety standards is based on MSHA's approval of the terms and conditions in that plan. A copy of the plan may be obtained from MSHA at the address noted above. MSHA finds that the granting of this exception to underground coal mine safety standards will not adversely affect the health and safety of miners. Mathies Mine is therefore granted an exception to all safety standards for underground coal mines governing mine ventilation, mine examinations, and electric equipment (30 CFR subparts D and F) for the duration of the experiment.

Dated: May 23, 2003.

Dave D. Lauriski,

Assistant Secretary for Mine Safety and Health.

[FR Doc. 03–13529 Filed 5–28–03; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (03–054)]

NASA Advisory Council; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council (NAC).

DATES: Tuesday, June 10, 2003, 8 a.m. to noon and 3 p.m. to 5 p.m; and Wednesday, June 11, 2003, 8 a.m. to noon.

ADDRESSES: National Aeronautics and Space Administration, Room MIC–6H46, overflow room MIC–7H46, 300 E Street, SW, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms.Kathy Dakon, Code IC, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–0732.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. Proceedings of the NAC will be shown live via video feed in the overflow room, MIC–7H46. The agenda for the meeting is as follows:

—Administrative Issues
—Informational Briefings:
  —a. Return to Flight
  —b. NASA Communications
  —c. Office of Space Science Programs
—Review NASA's Strategic Initiatives

Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide the following information: full name; gender; date/place of birth; citizenship; visa/greencard information (number, type, expiration date); employer/affiliation information (name of institution, address, country, phone); title/position of attendee. To expedite admittance, attendees can provide identifying information in advance by contacting Ms. Marla King via email at *marla.k.king@nasa.gov* or by telephone at 202–358–1148. Attendees will be escorted at all times.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

June W. Edwards,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 03–13456 Filed 5–28–03; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Corporate Federal Credit Union Bylaws

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final corporate Federal credit union bylaws.

SUMMARY: NCUA is updating the corporate Federal credit union (FCU) bylaws. This action is necessary because several of the bylaws had become outdated or obsolete. The amendments modernize and clarify the corporate FCU bylaws.

DATES: The final bylaws are effective June 30, 2003.

FOR FURTHER INFORMATION CONTACT: Kent D. Buckham, Director, Office of Corporate Credit Unions (OCCU), National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428 or telephone: (703) 518–6640.

SUPPLEMENTARY INFORMATION:

Background

Section 108 of the Federal Credit Union Act (the Act) requires the NCUA Board to prepare bylaws to be used by all federal credit unions (FCUs). 12 U.S.C. 1758. The Garn-St Germain Depository Institutions Act of 1982 authorized the NCUA Board to differentiate the activities of corporate credit unions (corporates) from natural person credit unions through rules, regulations, and orders of the NCUA Board. In recognition of the unique mission and operating needs of corporates, the NCUA Board, in coordination with the corporate credit union community, developed and adopted a set of standard Corporate Federal Credit Union Bylaws (bylaws) in March of 1983. Since then, the only revisions were in 1994, when the Board revised the provisions relating to Meetings of Members and Elections. 59 FR 59357, 59361 (November 17, 1994).

NCUA issued proposed bylaws in December 2002 to update, modernize and clarify the bylaws. 67 FR 79152 (December 27, 2002). In the past 20 years, significant regulatory, economic and institutional changes have taken place. The proposed revisions to the bylaws reflected the current legal, technological, and financial environment within which corporate credit unions operate. NCUA received 10 comments to the proposal. The commenters were supportive of the proposal, but raised several minor issues.

Summary of Comments to the Proposed Corporate FCU Bylaws

On December 19, 2002, the Board issued a Notice and Request for Comment on the Corporate Federal Credit Union Bylaws. *Id.* The Board received ten comments regarding the proposed bylaws: four from corporate FCUs, one from an FCU, one from a state chartered credit union, three from credit union trade organizations and one from a credit union league. The commenters supported NCUA's effort in updating the bylaws. They expressed appreciation for NCUA's solicitation of comments in regard to the proposed revisions to the bylaws. Generally, those commenting commended the agency's proposal to modernize the bylaws, making them more user friendly, removing outdated items and utilizing ''plain English.'' Two commenters suggested the dynamic working environment of corporates warrants a more frequent review of selected portions of the bylaws. Below is a summary of the comments.

General Areas for Review

NCUA's request for comment states that while corporates are strongly encouraged to adopt any final revised bylaws, they are not required to do so and may instead continue to follow currently approved bylaws or adopt only portions of the revised bylaws. Six commenters supported the flexibility proposed in the supplementary information section. Five of those six commenters requested that NCUA clarify that NCUA approval is not required to adopt portions of the revised bylaws. As the Board stated in the proposed bylaws, ''in an effort to achieve maximum participation,'' the Board will permit corporate FCUs ''to adopt portions of the revised bylaws.'' *Id.* at 79153. NCUA Board approval is not required.

Specific Areas for Review

Article III—Membership

Members Who Leave the Field of Membership

One commenter supported section 4 of the proposed bylaws that states a member of a corporate may remain a member of that corporate until the person or entity withdraws or is expelled. The commenter indicated that the proposed update brings the bylaws in line with NCUA's field of membership (FOM) policy allowing Federal corporates to apply for national FOMs. A trade association commenter also supported the proposed provision in this section permitting a corporate to restrict services to a member no longer in the FOM and addressing the termination of membership in the case of a member of a corporate converting to another form of financial institution. This section is retained as proposed.

Article IV—Shares of Members

Par Value

One commenter opposed the proposed revision in section 1 that eliminates the alternative of paying for a share in a corporate in installments and instead requires the purchase of a share to be made at the time of subscription. The commenter urged NCUA to retain the current bylaw provision giving credit unions the option to pay for corporate shares either in installments or at the time of subscription. The Board considered the comment but because for corporates, the business practicality of permitting the payment of shares in installments is unduly burdensome, it is retaining this revision as proposed.

Article V—Meetings of the Members

Special Meetings and Quorum

One commenter supported the provisions that relax both member requirements for calling a special meeting (section 3) and establishing a quorum (section 4). The commenter indicated that these proposed provisions will provide member credit unions with greater opportunity to provide input into decisions on special matters as they arise. This section is retained as proposed.

Article VI—Elections

Selection of Nominating Committee

In section 1 of this article, the Board proposed changing the term ''candidate'' to the term ''member'' in regard to nominating parties for vacant positions relative to elections. One commenter, a corporate credit union opposed the change in terms. The commenter noted its corporate does not have any members who are natural persons. All of the corporate's members are organizational members. The commenter believes the proposed change in terms would mean the corporate's nominating committee would be required to nominate a credit union or other organizational member for each upcoming vacancy on the board of directors. The Board agrees with the corporate's concern and will reinstate the term ''candidate'' in the final version of the revised bylaws.

Election Conduct

Five commenters supported the addition of electronic balloting, one citing that it will enhance efficiency of the operations of corporates. This section is retained as proposed.

Voting by Trustee

Section 4 prohibits voting by proxy and permits a member other than a natural person to vote through a designated agent. The Board is deleting the sentence that prohibits voting by a trustee because it has no applicability to corporates.

Reporting of Appointments and Election Results

Two commenters disagreed with the proposed addition of section 5 to this article. It requires corporates to notify NCUA of the names and addresses of certain officials and committee members. The commenters believe that the requirement is important but adequately addressed in the Federal Credit Union Act and need not be duplicated in the bylaws. This section was adapted from the Federal Credit Union (FCU) Bylaws for natural person FCUs. FCU Bylaws, Article V, section 6, October 1999. The Board considered the comment but believes that this issue is of sufficient importance to warrant its inclusion in the bylaws. The Board is retaining this revision as proposed.

Article VII—Board of Directors

Number

One commenter suggested a revision to the proposed wording of section 1. The first sentence states: ''The board consists of ____ members elected from among the members and/or designated representatives of members.'' The corporate proposed changing the ''and/or'' to ''and''. The commenter believes that the proposed change reflects the current practice of corporates to have a certain number of board members who are also designated representatives of members. The Board considered the corporate's comment but believes the current provision provides needed flexibility. The Board is retaining this section of the bylaws as proposed.

Suspension of Supervisory Committee Members

One commenter suggested a revision to the proposed wording of section 8. Section 8 provides that members of a corporate will decide, at a special meeting held not fewer than 7 nor more than 14 days after the suspension of a supervisory committee member whether the member will be removed or restored. The corporate believes that the 14 day time frame is far too short to provide adequate notice to members of a special meeting and recommends increasing this time frame to 30 days. The Board is not persuaded by the rationale offered, given the current technological alternatives available for providing timely notification. The Board is retaining this section of the bylaws as proposed.

Miscellaneous

Three commenters are concerned about corporate employees leaving the company's employ and then running for the corporate board. The basis for the concern is that former employees possess inside information and could potentially use this knowledge to inappropriately influence other board members. The commenters suggested NCUA consider adding a bylaw provision to this article that would prohibit employees from serving on the corporate's board of directors for a minimum of two years after termination of employment. The Board considered the comments and concluded that it is not appropriate to limit through a standard bylaw, those individuals who

are eligible to run for election. The Board believes this issue can be addressed through the request and approval of a nonstandard bylaw amendment if it is of particular concern to an individual corporate.

Article VIII—Board of Directors, Executive Committee, Asset/Liability Management Committee (ALCO), and Management Staff

Board Officers

Section 1 of this article identifies the titles of the board officers of a corporate. The titles include ''executive officer'' and ''assistant executive officer''. The proposed revision to Article VII, section 4, includes the terms ''chair'' and ''ranking vice-chair'' when referring to board officers. Four commenters recommended that the terms be amended in this Article to eliminate confusion in circumstances where corporate credit union presidents are often corporate credit union chief executive officers as well. The Board agrees. Revisions have been made to the applicable sections eliminating confusion relative to board officer titles.

Financial Officer

Section 5 provides that the financial officer is responsible for the management of the corporate unless the board employs a separate management official. A commenter noted that in the FCU Bylaws, it states that ''the financial officer manages this credit union *under the control and direction of the board*, unless the board has appointed a management official to act as general manager.'' FCU Bylaws, Article VII, section 6 (emphasis added). The commenter explained that the underlined language is missing from NCUA's proposed revision to the corporate Federal credit union bylaws. Due to the complexity of today's corporate credit union operations, the commenter is concerned about a board member having the power to also manage the corporate. The commenter strongly recommended that the underlined language from the FCU Bylaws be inserted into this section. It is pertinent to note that in section 6, Manager Other than Financial Officer, the underlined language is included. The Board agrees with the commenter and the underlined phrase will be inserted into section 5.

Manager Other Than Financial Officer

Section 6 of this article allows the board to employ a management official who is not a member of the board. Two commenters are concerned about a corporate board member becoming chief executive officer of a corporate credit union immediately after stepping down from the board. They believe the bylaws should prohibit this activity because of the potential for conflicts between the board member and the corporate's remaining management and the potential undue influence that such a board member might exert on the decision to terminate the prior chief executive officer. The commenters suggested NCUA consider a proposed revision prohibiting this activity. They suggested adopting as part of the corporate bylaws a 1991 standard bylaw amendment for natural person FCUs that states ''no director may be a paid employee of the credit union for a minimum of 2 years from the date the official terminates his/her position as a director unless the employee position to be filled exists as the result of a death or disability''. Federal Credit Union Standard Bylaw Amendments and Guidelines, October 1991. This provision is not in the current version of the FCU Bylaws for natural person credit unions. The Board considered the comments and concluded that, rather than having this restrictive policy apply to all corporates, this issue should be addressed through the request and approval of a nonstandard bylaw amendment if it is of particular concern to an individual corporate.

Article X—Supervisory Committee

Suspension of Directors, Executive Officers or Credit Committee Members

The commenter suggesting a revision to the timing for notices in current and proposed Article VII, section 8 recommended a corresponding change to section 5 of this article. Section 5 provides that the members of a corporate will decide, at a special meeting held not fewer than 7 nor more than 14 days after the supervisory committee suspends a director, executive officer, or member of the credit committee, whether the director, officer or member will be removed or restored. The commenter believes that the 14-day time frame is far too short to provide adequate notice to members of a special meeting and recommends increasing this time frame to 30 days. The Board is not persuaded by the rationale offered given the current technological alternatives available for providing timely notification. The Board is retaining this section of the bylaws as proposed.

Article XII—Operations Following an Attack on the United States or Catastrophic Occurrence Otherwise Rendering the Corporate Credit Union Inoperable

One commenter recommended deleting this provision of the bylaws to mirror the deletion made to the FCU Bylaws for natural person credit unions in October 1999. Another commenter, a trade association, remarked that its members do not believe this provision should be a bylaw topic. Both commenters believe contingency planning efforts are better left as an operational and supervisory issue rather than in a bylaw. The Board considered the comments but believes that this issue is of sufficient importance to warrant its inclusion in the bylaws. The Board is retaining this revision as proposed.

One commenter supported the addition of the ''catastrophic occurrence or contingency situation'' since they see that type of occurrence to be more likely to cause serious disruption of services than an attack on the United States. Another commenter, a trade association supported NCUA's provision regarding contingency planning in the event of attack on the United States or other catastrophic event. These sections are retained as proposed.

Contingency Plan

One commenter specifically disagreed with the addition of the (third) new section that requires the corporate credit union to maintain and periodically test an organization-wide contingency plan. The corporate believes this requirement is an operational matter that is adequately addressed in § 704.4(a) and (b) of the regulations. 12 CFR 704.4(a) and (b). The Board believes that this issue is of sufficient importance to warrant its inclusion in the bylaws. The Board is retaining this revision as proposed.

Indemnification

Four commenters suggested addressing indemnification in the bylaws. While this issue is addressed in section 701.33(c) of the NCUA Rules and Regulations, two corporates commenting on this issue had adopted an indemnification (nonstandard bylaw amendment) provision in their bylaws. The corporates' rationale for adopting an indemnification bylaw was to guard against the possibility that, after a dispute at the corporate that led to the departure of directors or other indemnified officials, a subsequent board of directors might try to eliminate the indemnification rights of the

departed personnel through changing policy. If the indemnification provisions are set forth in the bylaws, any such retroactive removal of the provision would have to be approved by NCUA. The Board believes that this issue is of sufficient importance to warrant its inclusion in the bylaws. The final revised bylaws include an indemnification provision modeled after the FCU Bylaws.

Agency Publication of Final Bylaws and Adoption by Corporates

The final bylaws provide a user friendly document for the internal governance of corporate FCUs. Every effort was made to use plain English in the bylaws. The final bylaws are identical to the proposed bylaws except as noted above in the summary of comments. A table of contents will be provided in the agency's publication of the bylaws that is distributed to corporates.

Corporate FCUs are strongly encouraged to adopt the final revised bylaws, but are not required to do so and may continue to use their previously approved bylaws. The Board, in an effort to achieve maximum participation by corporate FCUs, will allow them to adopt portions of the revised bylaws, if a corporate FCU finds that adoption of the entire revised bylaws is impracticable. The Board cautions corporate FCUs adopting only a portion of the revised bylaws to use extreme care because they run the risk of having inconsistent or conflicting bylaw provisions. Although the Act requires corporate FCUs to use the bylaws published by NCUA, corporate FCUs will continue to have the flexibility to request a nonstandard bylaw amendment if the need arises. 12 U.S.C. 1758. A corporate FCU must obtain approval from the Director of OCCU to adopt a nonstandard bylaw.

By the National Credit Union Administration Board on May 22, 2003.

Becky Baker,

Secretary of the Board.

Bylaws

Federal Credit Union, Charter No. _____
(A corporation chartered under the laws of the United States)

Article I. Definitions

Section 1. When used in these bylaws the terms:

(a) ''Act'' means the Federal Credit Union Act, as amended.

(b) ''Administration'' means the National Credit Union Administration.

(c) ''Regulation'' or ''regulations'' means rules and regulations issued by the National Credit Union Administration.

(d) ''Share'' or ''shares'' means any amount deposited for the credit of a member or other account holder and includes, but is not limited to, share accounts, share certificate accounts, share draft accounts, and nonmember accounts (however denominated) permitted by law.

(e) ''Board'' means board of directors of this corporate credit union.

Section 2. If included in the definition of the field of membership in the organization certificate (charter) of this corporate credit union, the term or expression ''organizations of such members'' means an organization or organizations composed of entities that are within the field of membership of this corporate credit union.

Article II. Name-Purposes

Section 1. The name of this corporate credit union is as stated in section 5 of the charter (approved organization certificate) of this corporate credit union.

Section 2. The purpose of this corporate credit union is to foster and promote the economic well-being, growth and development of its members through effective funds management, interlending, investment services and such other activities and services that may be beneficial to its members and are authorized by Act and regulations.

Article III. Membership

Section 1. The field of membership of this corporate credit union is limited to that stated in section 5 of its charter.

Section 2. Applications for membership eligibility under section 5 of the charter must be signed by the applicant on forms approved by the board. Upon approval of the application and upon subscription to a share with par value as established by the board in Article IV and the payment of a uniform entrance fee, if required by the board, the applicant is admitted to membership. Applications must be approved by a majority of the directors, a majority of the members of a duly authorized executive committee, or by a membership officer. If a membership application is denied, the reasons must be furnished in writing to the applicant upon written request.

Section 3. Membership of any member whose account contains less than the minimum required in Article IV, section 1 may be terminated in accordance with procedures established by the board of directors.

Section 4. Once a person or entity becomes a member that person or entity may remain a member until the person or organization chooses to withdraw or is expelled in accordance with the Act. A corporate credit union that wishes to restrict services to members no longer within the field of membership should specify the restrictions in this section. In the case of a member credit union that converts to another form of financial institution outside the field of membership, membership ceases at a mutually agreeable time not to exceed six months from the conversion date.

Section 5. A member may be expelled only in the manner provided by the Act.

Article IV. Shares of Members

Section 1. The par value of each share will be _____ (as determined by the board) and payable at the time of the subscription.

Section 2. Shares of a member may be transferred among the member's accounts or to another member in such manner as the board may prescribe.

Section 3. Unless otherwise provided by the board, shares may be withdrawn on any day when payment on shares may be made; provided that no member may withdraw shareholdings that are pledged as required security on loans without the written approval of the credit committee or a loan officer, except to the extent that such shares exceed the member's total primary and contingent liability to the corporate credit union.

Article V. Meetings of Members

Section 1. The annual meeting of the members must be held at such time and place as the board will determine and announce in the notice prescribed in section 2 of this Article.

Section 2. At least 75 days before the date of any annual meeting or 10 days before the date of any special meeting of the members, the secretary must give written notice to each member appearing on the records of this corporate credit union. Such notice must state the date, time, and location of the meeting and such other information as the board of directors determine consistent with these bylaws. Any meeting of the members, whether annual or special, may be held without prior notice, at any place or time, if all the members entitled to vote, who are not present at the meeting, waive notice in writing, before, during, or after the meeting. The notice for the annual meeting will advise the members of the deadlines for elections.

In the case of members who have previously consented to the electronic delivery of documents, said notice may be sent by electronic mail to the e-mail address that appears on the records of the corporate credit union.

Section 3. Special meetings of the members may be called by the chair or the supervisory committee as provided in these bylaws, or by applicable law or regulation, and may be held at any place permitted for the annual meeting. A special meeting must be called by the chair within 45 days of receipt of a request of 5 percent of the members as of the day of request; provided that a request of no more than 100 members is required. Notice must be given as provided in section 2 of this article and must state the purpose for which it is to be held. No business other than that related to this purpose may be transacted at the meeting.

Section 4. The lesser of 15 members or 20 percent of the membership constitutes a quorum at any annual or special meeting. If a quorum is not present on the date first designated for the meeting, an adjournment may be taken to a date not fewer than 7 days or more than 30 days thereafter, and a second notice will be given to all members setting forth the date, time, and place of the adjourned meeting. The members then present constitute a quorum, regardless of the number of members present.

Article VI. Elections

Section 1. At least 120 days before each annual meeting, the board of directors will appoint a nominating committee of not fewer than three members. It is the duty of the nominating committee to nominate at least one candidate for each vacancy, including any unexpired term vacancy, for which elections are being held, and to determine that the candidates nominated are agreeable to the placing of their names in nomination and will accept office if elected. The nominating committee files its nominations with the secretary of the corporate credit union at least 90 days prior to the annual meeting, and the secretary notifies in writing all members eligible to vote at least 75 days prior to the annual meeting that nominations for vacancies may also be made by petition signed by 5 percent of the members with a minimum of 5 and a maximum of 100.

Notice may be accomplished as prescribed in Article V, section 2.

The written notice must indicate that the election will not be conducted by ballot and there will be no nominations from the floor when there is only one nominee for each position to be filled. A brief statement of qualifications and biographical data in a form approved by the board of directors will be included for each nominee submitted by the nominating committee with the written notice to all eligible members. Each nominee by petition must submit a similar statement of qualifications and biographical data with the petition. The written notice must state the closing date for receiving nominations by petition. In all cases, the period for receiving nominations by petition must extend at least 30 days from the date of the petition requirement and the list of nominating committee's nominees are mailed to all members. To be effective, such nominations must be accompanied by a signed certificate from the nominee or nominees stating that they are agreeable to nomination and will serve if elected to office. Such nominations must be filed with the secretary of the corporate credit union at least 40 days prior to the annual meeting.

In carrying out their responsibilities, the nominating committee and board of directors must ensure that the requirements of § 704.14 (a) of the regulations are satisfied.

Section 2. All elections are determined by plurality vote. All elections will be by electronic device or mail ballot, subject to the following conditions:

(a) The election tellers will be appointed by the board of directors;

(b) If sufficient nominations are made by the nominating committee or by petition to provide more than one nominee for any position to be filled, the secretary, at least 30 days prior to the annual meeting, will cause either a printed ballot or notice of ballot to be mailed to all members eligible to vote;

(c) If the corporate credit union is conducting its elections electronically, the secretary will cause the following materials to be mailed to each eligible voter and the following procedures will be followed:

(1) One notice of balloting stating the names of the candidates for the board of directors and the candidates for other separately identified offices or committees are printed in order as determined by the draw of lots. The name of each candidate must be followed by a brief statement of qualifications and biographical data in a form approved by the board of directors.

(2) One instruction sheet stating specific instructions for the electronic election procedure, including how to access and use the system, and the period of time in which votes will be taken. The instruction will state that members without the requisite electronic device necessary to vote on the system may vote by mail ballot upon written or telephone request and specify the date the request must be received by the corporate credit union.

(3) It is the duty of the tellers of election to verify, or cause to be verified the name of the voter and the corporate credit union account number as they are registered in the electronic balloting system. It is the duty of the tellers to test the integrity of the balloting system at regular intervals during the election period.

(4) Ballots must be received no later than midnight 5 calendar days prior to the annual meeting.

(5) Voting will be closed at the midnight deadline specified in subsection (4) hereof and the vote will be tallied by the tellers. The result must be verified at the annual meeting by the secretary and the chair will make the result of the vote public at the annual meeting.

(6) In the event of malfunction of the electronic balloting system, the board of directors may in its discretion order elections be held by mail ballot only. Such mail ballots must conform to section 2(d) of this Article and must be mailed to all eligible members 30 days prior to the annual meeting. The board may make reasonable adjustments to the voting time frames above, or postpone the annual meeting when necessary, to complete the elections prior to the annual meeting.

(d) If the corporate credit union is conducting its election by mail ballot, the secretary will cause the following materials to be mailed to each member and the following procedures will be followed:

(1) One ballot, clearly identified as such, on which the names of the candidates for the board of directors and the candidates for other separately identified offices or committees are printed in order as determined by the draw of lots. The name of each candidate will be followed by a brief statement of qualifications and biographical data in a form approved by the board of directors.

(2) One ballot envelope clearly marked with instructions that the completed ballot must be placed in that envelope and sealed.

(3) One identification form to be completed so as to include the name, address, signature and corporate credit union account number of the voter.

(4) One mailing envelope in which the voter, pursuant to instructions provided with the mailing envelope, must insert the sealed ballot envelope and the identification form, and which must have postage prepaid and be preaddressed for return to the tellers.

(5) When properly designed, one form can be printed that represents a combined ballot and identification form, and postage prepaid and preaddressed return envelope.

(6) It is the duty of the tellers to verify, or cause to be verified, the name and corporate credit union account number of the voter as appearing on the identification form; to place the verified identification form and the sealed ballot envelope in a place of safekeeping pending the count of the vote; in the case of a questionable or challenged identification form, to retain the identification form and sealed ballot envelope together until the verification or challenge has been resolved.

(7) Ballots mailed to the tellers must be received by the tellers no later than midnight 5 days prior to the date of the annual meeting.

(8) Voting will be closed at the midnight deadline specified in subsection (7) hereof and the vote will be tallied by the tellers. The result will be verified at the annual meeting by the secretary and the chair will make the result of the vote public at the annual meeting.

Section 3. Nominations may be in the following order:

(a) Nominations for directors;

(b) Nominations for credit committee members, if applicable; elections may be by separate ballots following the same order as the above nominations or, if preferred, may be by one ballot for all offices.

Section 4. Members cannot vote by proxy, but a member other than a natural person may vote through an agent designated in writing for the purpose. No voting representative may serve as a voting representative of more than one member. Irrespective of the number of shares, no member has more than one vote.

Section 5. The names and addresses of members of the board, board officers, executive committee, and members of the credit committee, if applicable, and supervisory committee must be forwarded to NCUA in accordance with the Act and regulations in the manner as may be required by NCUA.

Article VII. Board of Directors

Section 1. The board consists of ____ members elected from among the members and/or designated representatives of members. The number of directors may be changed to an odd number not fewer than five by resolution of the board. No reduction in the number of directors may be made unless corresponding vacancies exist as a result of deaths, resignations, expiration of terms of office, or other actions provided by these bylaws. A copy of the resolution of the board covering any increase or decrease in the number of directors must be filed with the official copy of the bylaws of this corporate credit union.

Section 2. Regular terms of office for directors must be periods of either 1, 2 or 3 years as the board determines; provided that all regular terms must be for the same number of years and until the election and qualification of successors. The regular terms must be fixed at the beginning, or upon any increase or decrease in the number of directors, so that approximately an equal number of regular terms must expire at each annual meeting.

Section 3. Any vacancy on the board, credit committee, or supervisory committee

will be filled by vote of a majority of the directors then holding office. Directors and credit committee members so appointed will hold office only until the next annual meeting, at which any unexpired terms will be filled by vote of the members, and until the qualification of their successors. Members of the supervisory committee so appointed will hold office until the first regular meeting of the board following the next annual meeting of members at which the regular term expires and until the appointment and qualification of their successors.

Section 4. A regular meeting of the board must be held each month at the time and place fixed by resolution of the board. One regular meeting each calendar year must be conducted in person. If a quorum is present in person for the annual in person meeting, the remaining board members may participate using audio or video teleconference methods. The other regular meetings may be conducted using audio or video teleconference methods. At least 7 days prior to each meeting, the secretary will cause the following information to be distributed to each director:

(a) Minutes of the last meeting;

(b) Reports of officers, standing committees, or of any special committee;

(c) Special orders, or matters which have been assigned priority; and

(d) Any written information on unfinished business or new business that has been given to the secretary by any director.

Each participant of a teleconference meeting at the next regularly convened meeting of the board at which the participant is present must sign minutes of audio or video teleconference meetings.

The chair, or in the chair's absence the ranking vice chair, may call a special meeting of the board at any time and must do so upon written request of a majority of the directors then holding office. Unless the board prescribes otherwise, the chair, or in the chair's absence the ranking vice chair, will fix the time and place of special meetings. Notice of all meetings will be given in such manner as the board may from time to time by resolution prescribe. Special meetings may be conducted using audio or video teleconference methods.

Section 5. The board has the general direction and control of the affairs of this corporate credit union and is responsible for establishing programs to achieve the purposes of this corporate credit union as stated in Article II, section 2, of these bylaws. While the board may, as authorized in the bylaws, delegate the performance of administrative duties, the board is not relieved from its responsibility for their performance.

Section 6. A majority of the number of directors constitutes a quorum for the transaction of business at any meeting thereof, but fewer than a quorum may adjourn from time to time until a quorum is in attendance.

Section 7. If a director or credit committee member fails to attend three consecutive regular meetings of the board or credit committee; respectively, or otherwise fails to perform any of the duties devolving upon him/her as a director or credit committee member, his/her office may be declared vacant by the board and the vacancy filled as herein provided. The board may remove any board officer from office for failure to perform the duties thereof, after giving the officer reasonable notice and opportunity to be heard.

When any board officer, membership officer, executive committee member, or Asset/ Liability Management Committee (ALCO) member, or credit committee member is absent, disqualified, or otherwise unable to perform the duties of his/her office, the board may, by resolution, designate another member of this corporate credit union to act temporarily in his/her place. The board may also, by resolution, designate another member or members of this corporate credit union to act on these committees, when necessary, in order to attain a quorum.

Section 8. Any member of the supervisory committee may be suspended by a majority vote of the board of directors. The members of this corporate credit union will decide, at a special meeting held not fewer than 7 nor more than 14 days after any such suspension, whether the suspended committee member will be removed from or restored to the supervisory committee.

Section 9. No member of the board of directors may receive any compensation or benefit solely as a result or by virtue of service as a member of the board of directors except for reimbursement for reasonable expenses incurred in the performance of official duties and as provided for in Article VIII of these bylaws.

Section 10. The board of directors will determine that monthly financial statements are prepared showing the condition of this corporate credit union. These financial statements will be readily available to members on a monthly basis in a manner deemed appropriate by the board.

Article VIII. Board Officers, Executive Committee, Asset/Liability Management Committee (ALCO), and Management Staff

Section 1. The board officers of this corporate credit union are comprised of a chair, one or more vice chairs, a financial officer, and a secretary, all of whom will be elected by the board and from their number. The board will determine the title and rank of each board officer and record them in the addendum to this article. One board officer, the _____, may be compensated for his/her services to such extent as may be determined by the board. If more than one vice chair is elected, the board will determine their rank as first vice chair, second vice chair, and so on. The offices of financial officer and secretary only may be held by the same person. Unless removed as provided in these bylaws, the officers elected at the first meeting of the board will hold office until the first meeting of the board following the first annual meeting of the members and until the election and qualification of their respective successors.

Section 2. Board officers will be elected at the first meeting of the board following the annual meeting of the members, which must be held not later than 7 days after the annual meeting. The elected officers will hold office until the first board meeting following the next annual meeting of the members and until the election and qualification of their respective successors; provided that any person elected to fill a vacancy caused by the death, resignation, or removal of an officer is elected by the board to serve only for the unexpired term of such officer and until a successor is duly elected and qualified.

Section 3. The chair will call and will preside at all meetings of the members and at all meetings of the board unless disqualified through suspension by the supervisory committee. The chair also performs such other duties as customarily appertain to the office of the chair or as may be directed to perform by resolution of the board not inconsistent with the Act and regulations and these bylaws.

Section 4. The available ranking vice chair has and may exercise all the powers, the authority, and the duties of the chair during the chair's absence or inability to act.

Section 5. Unless the board employs a separate management official, the financial officer is responsible for the management of the corporate credit union under the control and direction of the board and has such authority and such powers as delegated by the board to conduct business from day to day. If actually managing the corporate credit union, the financial officer may be compensated as may be determined by the board. The financial officer may employ or designate one or more assistants, as well as other employees, and may authorize them to perform any of the duties devolving on the financial officer, including the signing of checks. When so designated by the financial officer or the board, any assistant may also act as financial officer during the temporary absence of the financial officer or in the event of the financial officer's inability to act.

Section 6. The board may employ a management official who is not a member of the board and who is under the direction and control of the board, and has all of the duties, powers, rights and responsibilities of the financial officer described in section 5. The board determines the title and the rank of each management official and records them in the addendum to this article.

Section 7. The secretary causes to be prepared and maintained full and correct records of all meetings of the members and of the board, which records will be prepared within 7 days after the respective meetings. The secretary promptly informs NCUA in writing of any change in the address of the office of this corporate credit union, or the location of its principal records. The secretary gives, or causes to be given, in the manner prescribed in these bylaws, proper notice of all meetings of the members, and performs such other duties as he/she may be directed by resolution of the board not inconsistent with the Act, regulations and these bylaws.

The board may employ one or more assistant secretaries, none of whom may also hold office as chair, vice chair, or financial officer, and may authorize them under direction of the secretary to perform any of the duties devolving on the secretary.

Section 8. The board may appoint an executive committee of not fewer than three

directors to act for it with respect to specifically delegated functions and subject to such limitations as prescribed by the board.

Section 9. The board may appoint one or more membership officers to approve applications for membership under such conditions as the board and these bylaws may prescribe. Such membership officer or officers may not be a person or persons authorized to disburse funds.

Section 10. The board will appoint an ALCO composed of not less than three, including at least one board member, to have charge of making investments under rules and procedures established by the board.

Section 11. No member of the executive committee, ALCO or membership officer may be compensated as such. Members of the executive committee, ALCO, and membership officers serve at the pleasure of the board of directors.

Addendum

The title and rank of the board officers and management officials of this corporate credit union are as follows:

(a) The chair is to have the title of _____.

(b) The vice chair is to have the title of _____.

(c) The financial officer is to have the title of _____.

(d) The assistant financial officer is to have the title of _____.

(e) The recording officer is to have the title of _____.

(f) The assistant recording officer is to have the title of _____.

(g) The management official is to have the title of _____.

(h) The assistant management official is to have the title of ____.

Article IX. Credit Committee

Section 1. The board must determine whether or not this corporate credit union will have a credit committee, and if so, whether the committee members will be elected by the membership or appointed by the board. The board's determination is recorded in the addendum to this Article. If this corporate credit union has a credit committee, either elected or appointed, sections 2 through 7 of this Article apply. If this corporate credit union does not have a credit committee, the board will establish by resolution the procedures for appointing loan officers, delegating authority to the loan officers, and for appeal of loan officer decisions to the board of directors in accordance with applicable law and regulation.

Section 2. The credit committee consists of ___ members. Members of the credit committee must be selected from among the members of the corporate credit union and/or the designated representatives of members or qualified corporate credit union staff. The number of members of the credit committee may be changed to an odd number not fewer than 3 nor more than 7 by resolution of the board. No reduction in the number of members may be made unless corresponding vacancies exist as a result of deaths, resignations, expiration of terms of office, or other actions provided by these bylaws. A copy of the resolution of the board covering any increase or decrease in the number of committee members must be filed with the official copy of the bylaws of this corporate credit union.

Section 3. Regular terms of office for credit committee members are for periods of either 1, 2, or 3 years as the board will determine; provided that all regular terms are for the same number of years and until the election and qualification of successors. The regular terms are fixed at the beginning, or upon any increase or decrease in the number of committee members, so that approximately an equal number of regular terms expire at each annual meeting.

Section 4. The credit committee chooses from their number a chairman and a secretary. The secretary of the committee prepares and maintains full and correct records of all actions taken by it, and such records must be prepared within 3 days after the action. The offices of chairman and of secretary may be held by the same person.

Section 5. The credit committee may, by majority vote of its members, appoint one or more loan officers to serve at its pleasure and delegate its powers to such loan officers.

Section 6. The credit committee or loan officer must inquire into the financial condition of each loan applicant. No loan or line of credit will be made unless approved by the committee or a loan officer in accordance with applicable law and regulations.

Section 7. Subject to the limits imposed by law, regulation, these bylaws, and the general policies of the board, the credit committee, or a loan officer, will determine the security, if any, required for each application and the terms of repayment.

Addendum

(a) This corporate credit union (1) will, (2) will not (delete one) have a credit committee (date of board action _____).

(b) The members of the credit committee of this corporate credit union will be: (1) Elected by the members (2) appointed by the board of directors (delete one or indicate not applicable) (date of board action _____).

Article X. Supervisory Committee

Section 1. The supervisory committee is appointed by the board from among the members and/or from among the members' designated representatives. The board determines the number of members on the committee, which may not be fewer than three nor more than five. No member of the credit committee or any employee of this corporate credit union may be appointed to the committee. Regular terms of committee members are for periods 1, 2, or 3 years as the board determines; provided that all regular terms are for the same number of years and until the appointment and qualification of successors. The regular terms expire at the first regular meeting of the board following each annual meeting.

Section 2. The supervisory committee members choose from among their number a chairman and a secretary. The secretary of the supervisory committee prepares, maintains, and has custody of full and correct records of all actions taken by it. The same person may hold the offices of chairman and of secretary.

Section 3. The supervisory committee causes to be made such audits and to prepare and submit such written reports to the board and the members as are required by the Act and regulations.

Section 4. The supervisory committee verifies or causes to be verified the accounts of members in accordance with the Act and regulations.

Section 5. By unanimous vote, the supervisory committee may suspend until the next meeting of the members any director, executive officer, or member of the credit committee. In the event of any such suspension, the supervisory committee will call a special meeting of the members to act on said suspension, which meeting will be held not fewer than 7 nor more than 14 days after such suspension. The chairman of the committee will act as chairman of the meeting unless the members select another person to act as chairman.

Section 6. By the affirmative vote of a majority of its members, the supervisory committee may, after notification to the board, call a special meeting of the members to consider any violation of the provisions of the Act or of the regulations, or of the charter, or of the bylaws of this corporate credit union, or to consider any practice of this corporate credit union the committee deems to be unsafe or unauthorized.

Article XI. General

Section 1. The officers, directors, members of committees, and employees of this corporate credit union must hold in confidence all transactions of this corporate credit union with its members and all information respecting their business affairs, except when permitted by state or Federal law.

Section 2. No director, committee member, officer, agent, or employee of this corporate credit union may participate in any manner, directly, or indirectly, in the deliberation upon or the determination of any question affecting his/her pecuniary interest or the pecuniary interest of any corporation, partnership, or association (other than this corporate credit union) in which he/she is directly or indirectly interested. In the event of the disqualification of any director respecting any matter presented to the board for deliberation or determination, such director must withdraw from such deliberation or determination and, in such event, the remaining qualified directors present at the meeting, if constituting a quorum with the disqualified director or directors, may exercise with respect to this matter, by majority vote, all the powers of the board. In the event of the disqualification of any member of the credit committee, ALCO or the supervisory committee, such committee member must withdraw from such deliberation or determination.

Section 3. The board has the right, at any time, to impose fees for such services and activities, as it deems necessary or desirable.

Section 4. (a) The corporate may elect to indemnify to the extent authorized by (check one) ( ) law of the state of ____ or ( ) Model

Business Corporation Act the following individuals from any liability asserted against them and expenses reasonably incurred by them in connection with judicial or administrative proceedings to which they are or may become parties by reason of the performance of their official duties: (Check as appropriate) ( ) current officials, ( ) former official, ( ) current employees, ( ) former employees.

(b) The corporate credit union may purchase and maintain insurance on behalf of the individuals indicated in (a) above against any liability asserted against them and expenses reasonably incurred by them in their official capacities and arising out of the performance of their duties to the extent such insurance is permitted by the applicable state law or the Model Business Corporation Act.

(c) The term ''official'' in this bylaw means a person who is a member of the board of directors, supervisory committee, other volunteer committee (including elected or appointed loan officers or membership officers) established by the board of directors.

Article XII. Operations Following an Attack on the United States or Catastrophic Occurrence Otherwise Rendering the Corporate Credit Union Inoperable

Section 1. In the event of an attack upon the United States, or other catastrophic occurrence causing a contingency situation, the officers and employees of the corporate credit union will continue to conduct the affairs of the corporate credit union under such guidance from the directors as may be available and subject to conformance with any government directives during the emergency.

Section 2. In the event of an attack upon the United States, catastrophic occurrence, or a contingency situation, of sufficient severity to prevent the conduct and management of the affairs and business of the corporate credit union by its regularly elected directors, officers, and properly constituted committees as contemplated by these bylaws, any three available members of the then incumbent board of directors will constitute a quorum of the board of directors for the full conduct and management of the affairs and business of the corporate credit union including the approval of loans to members if the regularly elected credit committee is not available. In the event of the unavailability at such time of three members of the board, the vacancies, in order to provide a quorum of three, will be filled by a succession list established by the board of directors.

Section 3. The corporate credit union will maintain and periodically test an organization-wide contingency plan that addresses all reasonable emergency and disaster scenarios.

This bylaw is subject to implementation by resolutions of the board of directors passed from time to time for that purpose, and any provisions of these bylaws (other than this section) and any resolutions which are contrary to the provisions of this section or to the provisions of any such implemented resolutions will be suspended until a regularly constituted board of directors can be obtained.

Article XIII. Amendments of Bylaws and Charter

Section 1. Amendments of these bylaws may be adopted and amendments of the charter may be requested by the affirmative vote of two-thirds of the authorized number of members of the board at any duly held board meeting, if the members of the board have been given prior written notice of the meeting and the notice has contained a copy of the proposed amendment or amendments. No amendment of the bylaws or charter becomes effective until approved in writing by NCUA.

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OFFICE OF MANAGEMENT AND BUDGET

Performance of Commercial Activities

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Revision to Office of Management and Budget Circular No. A–76, ''Performance of Commercial Activities.''

SUMMARY: The Office of Management and Budget (OMB) is making revisions to Circular No. A–76 to improve the management of commercial activities. The revisions: (1) Strengthen application of public-private competition, so agencies may realize improved performance of commercial activities, especially those that are performed by government personnel without competition or converted to contract without consideration of the government's capabilities; (2) incorporate additional principles of the Federal Acquisition Regulation (FAR) into the public-private competition process, including the ability to conduct an expanded best value cost-technical tradeoff source selection process; (3) make agencies accountable to taxpayers for results achieved from public-private competitions, irrespective of the source or sector that performs the work; and (4) provide guidance for the transparent development of inventories of commercial and inherently governmental activities.

The revised Circular replaces the current OMB Circular No. A–76. The revised Circular also supersedes and rescinds the following documents: OMB Circular No. A–76 Revised Supplemental Handbook (Revised 2000), March 1996; OMB Circular No. A–76 Transmittal Memoranda Nos. 1–25; and Office of Federal Procurement Policy (OFPP) Policy Letter 92–1, *Inherently Governmental Functions*, September 23, 1992.

DATES: *Effective Date*: This revised Circular is effective May 29, 2003.

Applicability: The revised Circular shall apply to inventories required, and streamlined and standard competitions initiated, after the effective date. Direct conversions and cost comparisons, including streamlined cost comparisons, initiated but not completed by the effective date shall be covered by the revised Circular to the following extent. Direct conversions and streamlined cost comparisons shall be converted to streamlined or standard competitions under the revised Circular. Cost comparisons for which solicitations have not been issued before the effective date shall be converted to standard competitions under the revised Circular or, at the agency's discretion if permitted by the revised Circular, to streamlined competitions. The Circular in effect prior to this revision shall govern cost comparisons for which solicitations have been issued, unless agencies, at their discretion, convert such cost comparisons to standard competitions under the revised Circular, or, if permitted by the revised Circular, to streamlined competitions.

FOR FURTHER INFORMATION CONTACT: Office of Federal Procurement Policy, NEOB Room 9013, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503 (tel: (202) 395–3501 or 7808).

Availability: Copies of OMB Circular A–76, as revised by this notice, may be obtained at the OMB home page at *http://www.whitehouse.gov/OMB/circulars/index.html#numerical*. Paper copies of any of the documents identified above may be obtained by calling OFPP (tel: (202) 395–7579).

SUPPLEMENTARY INFORMATION:

A. Overview

To improve program performance to citizens and lower costs for taxpayers, OMB is making significant revisions to the processes and practices for determining whether a commercial activity will be performed by a public or private source. The revisions to OMB Circular No. A–76:

- Increase visibility into government management by requiring agencies to develop lists of their commercial and inherently governmental activities;
- Facilitate strategic decision making by ensuring effective agency planning for public-private competitions;
- Promote better service to our citizens by clarifying and simplifying the processes used to make competitive selections between public and private service providers;
- Close loopholes that diminish the return on taxpayer investment by: (i)

eliminating direct conversions and (ii) requiring that commercial activities competed under this Circular be periodically recompeted to ensure that the cost and quality of performance remain reasonable;

• Provide a level playing field for public-private competitions to ensure that commercial activities are performed by the best source at the lowest possible cost;

• Improve public trust by incorporating appropriate mechanisms of transparency, fairness, and integrity into public-private competition; and

• Strengthen accountability by: (i) centralizing agency oversight, (ii) holding public sector service providers to the same performance standards as those imposed on private sector providers, and (iii) requiring that the performance of service providers (both public and private) be tracked so that current experiences may inform and improve future decisions.

In addition to making significant substantive changes, OMB is modifying the organization of the Circular to improve clarity and ease of use. The main body of the Circular describes overarching policy tenets and the scope of agency responsibilities. The procedures for carrying out these policies are set forth in three attachments:

Attachment A, Inventory Process, describes how agencies develop lists of commercial and inherently governmental activities.

Attachment B, Public-Private Competition, identifies the required steps for conducting competitions between the public and private sectors (*e.g.*, planning, soliciting, negotiating), making performance decisions, and tracking implementation.

Attachment C, Calculating Public-Private Competition Costs, defines how agencies determine the cost of public sector performance and compare these costs to a private sector offer.

A fourth attachment, Attachment D, Acronyms, Definitions, and Index provides a detailed glossary and index of key terms used in the Circular and its attachments.

The proposed Circular would have incorporated long-standing limitations imposed on federal agencies regarding the reimbursable services they provide to state and local government. OMB Circular No. A–97, *Provision of Specialized or Technical Services to State and Local Units of Government by Federal Agencies Under Title III of the Intergovernmental Cooperation Act of 1968*, currently implements these requirements. Circular No. A–97 remains in effect as a separate, stand-alone Circular, and is unchanged by the final revisions to Circular No. A–76.

B. Background

Federal agencies rely on a mix of public and private sector sources to perform a wide variety of commercial activities. OMB Circular No. A–76 establishes the policies and procedures for identifying commercial activities and determining whether these activities should be provided by a private sector provider through a contract, by government personnel through a letter of obligation, or by a public reimbursable source (another agency) through a fee-for-service agreement.

Before an agency shifts commercial work from one source to another (*e.g.*, to or from performance by government personnel to performance by a contractor or public reimbursable source), Circular No. A–76 historically has required the agency to conduct a public-private competition in which the cost of performance is compared between the public and private sectors. The Circular has traditionally required agencies to perform a ''cost comparison'' by:

• Developing a performance work statement (PWS);

• Creating a management plan to determine the government's ''most efficient organization'' (MEO);

• Establishing an in-house government cost estimate that is certified by an independent reviewing official;

• Issuing a solicitation in accordance with the FAR seeking offers from private sector and public sector sources, except for the in-house source, whose cost estimate is submitted and evaluated independently;

• Identifying the best offer submitted in response to the solicitation and comparing it to the in-house estimate; and

• Making a decision based on the lowest cost alternative, which is subject to review under an administrative appeals process.

The Circular has recognized a variety of circumstances in which agencies are not required to conduct cost comparisons. For example, the Circular has allowed agencies to directly convert work to or from the private sector without cost comparison under certain circumstances, such as where an activity was or would be performed by an aggregate of 10 or fewer ''full-time-equivalent'' employees (FTEs). For additional discussion regarding the mechanics of Circular No. A–76, *see* 67 FR 69769, 69770–71 (November 19, 2002).

On November 19, 2002, OMB issued a notice in the **Federal Register** of proposed changes to Circular No. A–76 to significantly improve the procedures used to conduct, and the results achieved from, competitions between public and private sources. The changes OMB proposed were intended to address recurring complaints about the Circular's effectiveness. More than 700 public comments were submitted to OMB in response to the **Federal Register** notice. For a description of the proposed changes to the Circular and the accompanying Supplemental Handbook (hereinafter collectively referred to as the ''prior Circular''), *see* 67 FR 69769, 69771–74. For copies of the public comments on the proposed revisions, *see http://www.omb.gov*.

The next section of this preamble discusses the new features of the revised Circular, including its relationship to the President's Management Agenda. The discussion highlights the most significant public comments and explains how these comments are addressed in the revised Circular.

C. An Improved Framework for Managing the Government's Commercial Activities

The Administration's general policy is to rely on competition to select the providers of commercial activities. This policy is supported by published reports and historical data demonstrating that public-private competition generates significant cost savings, efficiency, and innovation.

Despite the benefits that public-private competition generates, many of the government's 850,000 FTEs that agencies have identified as performing commercial activities (nearly half of all federal employees) remain insulated from the dynamics of competition. To reverse this trend, the President's Management Agenda called upon agencies to develop plans for opening their commercial activities to the discipline of competition. In response, agencies across government have developed tailored plans that lay the foundation for institutionalizing public-private competitions.

Circular No. A–76 seeks to ensure that competition plans—and the President's broader vision of a market-based government—are successfully implemented. The revisions to the Circular achieve this result by significantly improving the processes for applying public-private competitions to government-performed commercial activities.

In particular, the revised Circular: (1) Facilitates strategic use of competition as a tool to improve overall agency

performance, (2) ensures fairness, integrity, and transparency in sourcing decisions, and (3) strengthens agency accountability for achieving results.

1. Facilitating Strategic Use of Competition

The revised Circular seeks to promote strategic decision making by ensuring that application of public-private competition results in performance by the best available source—irrespective of the sector. The revised Circular also aims to make processes clear and accommodate agency needs.

a. Competition-based Policy Orientation

The revised Circular, like the prior Circular, relies on competition as the foundation for determining whether government personnel should perform a commercial activity. *See* ¶ 4.c. of the revised Circular. The revised Circular requires use of either streamlined or standard competitions. The agency's competitive sourcing official (CSO)—*i.e.*, a specific agency official responsible within the agency for implementing the Circular—must justify, in writing, most decisions to exempt a commercial activity performed by government personnel from competition. *See* ¶ 5.b. of the revised Circular. In addition, deviations from the Circular's policies or the procedures set forth in the attachments must be approved by OMB. *See* ¶ 5.c. of the revised Circular.

i. *Emphasis on sector neutral competition*. Because OMB seeks to emphasize selection of the best service provider, as determined through competition, the revised Circular deletes a longstanding statement that the government should not compete with its citizens. Various commenters opposed the deletion, arguing that an important message will be lost regarding the significant role the private sector plays in facilitating the effective operation of government. OMB appreciates the critical contributions made by the private sector. Without the private sector, the government would not be able to meet the many needs of our citizenry. Deletion of the ''reliance'' statement from the revised Circular is not intended to denigrate this contribution. Nor does this action signal a retreat from the Administration's commitment to a market-based government that is unafraid of competition, innovation, and choice. The deletion is simply meant to avoid a presumption that the government should not compete for work to meet its own needs. Such a suggestion conflicts with the Circular's main function of providing policies and procedures to determine the best service provider—irrespective of the sector the provider represents.

The main policy tenets of the Circular have been refined to ensure that government performance of commercial activities does not result in unfair competition. In particular, a new proviso has been added to make clear that, with rare exception, an agency shall not perform work as a contractor or subcontractor to the private sector. *See* ¶ 4.l. of the revised Circular. In addition, the Circular will continue to prohibit an agency from reorganizing or restructuring a commercial activity to circumvent the Circular. *See* ¶5.f. of the revised Circular. As a more general matter, the revised Circular is intended to encourage greater trust and more robust participation in public-private competition by both sectors through processes that promote fairness, integrity, and transparency.

ii. *Establishment of competition timeframes.* Timeframe standards have been incorporated into the revised Circular to motivate agencies to complete competitions and to instill greater confidence that agencies will follow through on their plans. Current processes have been criticized for allowing agencies to extend public-private competitions indefinitely. Under the revised Circular, a standard competition must generally be conducted within a 12-month period beginning on the date the competition is publicly announced and ending on the date a performance decision is made. *See* ¶¶ D.1. & D.6.b. of Attachment B. A standard competition is the general competitive process provided by the revised Circular when an agency selects a provider based on formal offers or tenders submitted in response to an agency solicitation.

While a majority of the commenters supported the concept of time limits, there was considerable disagreement over the appropriate time limits. Several agency commenters requested that the timeframes for a standard competition be lengthened by several months and that greater leeway be given to agencies in need of extensions. Some commenters also complained that the 15-day time limit in the proposed Circular for use of streamlined processes is unrealistic.

The revised Circular continues to impose a 12-month limit as a general rule. In addition to instilling confidence in the process, time limits ensure that the benefits of competition are realized. However, to provide sufficient flexibility to the agencies, the revised Circular provides that the CSO, without delegation, may extend the 12-month period by 6 months with notification to OMB. The revised Circular does not adopt a provision in the proposed Circular that would have allowed the CSO (referred to as the ''4.e. official'' in the proposed Circular) to waive the one-year completion requirement at announcement of the competition and set an alternative completion date if the competition was particularly complex and notification was provided to OMB. However, if specified timetables are insufficient, an agency could seek longer completion periods using the Circular's deviation procedures. *See* ¶ 5.c. of the revised Circular.

As discussed below, the revised Circular significantly refines the framework for using streamlined processes. In doing so, the Circular modifies the proposed timeframes. Specifically, a streamlined competition must be completed within 90 calendar days from public announcement (described below) to performance decision unless the CSO grants a time limit waiver. Time limit waivers may not exceed 45 calendar days, for a maximum of 135 calendar days from public announcement to performance decision. If an agency cannot complete an announced streamlined competition within the time limit, the agency must either convert the streamlined competition to a standard competition or request an extension from OMB using the deviation procedure in paragraph 5.c. of the Circular. *See* ¶ C.2. of Attachment B.

For added transparency, the revised Circular calls for public announcements of certain key actions taken in connection with either standard or streamlined competitions. In particular, agencies must publicly announce the beginning of competitions, performance decisions made at the end of a competition, and any cancellation of an announced competition. Announcements must be made through FedBizOpps, *http://fedbizopps.gov,* the government-wide point of entry on the Internet for information on federal business opportunities. FedBizOpps is a user-friendly web site that is well known to service providers wishing to help federal agencies meet their missions. Announcements of competition and performance decisions must also be publicized locally. *See* ¶ B. of Attachment B.

iii. *Elimination of direct conversions and creation of new streamlined competition process.* The revised Circular makes a number of modifications regarding the handling of activities involving 65 or fewer FTEs. These changes seek to instill greater use of public-private competition for small

activities in a highly flexible and minimally burdensome, but fully accountable, manner.

Despite strong policy statements favoring public-private competitions, a number of commenters pointed out that the long-standing practice of permitting ''direct conversions'' (*e.g.*, typically for work performed by 10 or fewer FTEs) undermines this policy. Until now, under the prior Circular, agencies have been allowed to convert activities from public to private sector performance, or the reverse, under certain circumstances without public-private competition. Commenters asserted that, overall, this authority encourages agencies to go directly to contract as a matter of administrative convenience, even where a more efficient, cost-effective government organization could be the better alternative.

OMB agrees that agencies may be foregoing opportunities to reap savings and make better economic decisions through public-private competitions when they undertake a direct conversion. At the same time, OMB appreciates that the current processes for public-private competition are often time-consuming, costly, and burdensome for use under the conditions in which direct conversions are typically applied. In addition, while the prior Circular provided for a streamlined cost comparison process for evaluating public and private sector performance for commercial activities performed by 65 or fewer FTEs, flexibility has been limited.

The revised Circular builds on the foundation created by the prior Circular's streamlined process, by adding flexibility and accountability. For activities performed by 65 or fewer FTEs, the streamlined process enables agencies to efficiently capture the benefits of public-private competition without the burdens associated with current processes. *See* ¶¶ A.5.b. and C. of Attachment B.

The new streamlined competition gives agencies considerable latitude to make cost-effective choices. For example, when determining an estimated contract price for performing the activity with a private sector source, an agency may use documented market research or solicit proposals in accordance with the FAR. *See* ¶ C.1.b. of Attachment B. Agencies are free to use streamlined acquisition tools, such as a Multiple Award Schedules contract (*see* FAR Subpart 8.4) to obtain proposals from the private sector. In light of the significant efficiencies offered by the new streamlined competition process and the general goal of relying on public-private competitions, the revised Circular eliminates direct conversions.

The revised Circular incorporates a number of safeguards to ensure that agencies act as responsible stewards when using streamlined procedures. First, unlike the current procedures for streamlined cost comparisons, the revised Circular requires agencies to publicly announce both the start of a streamlined competition and the performance decision made by the agency. *See* ¶ B. of Attachment B. The notice announcing the initiation of a competition must include, among other things, the activity being competed, incumbent service providers, number of government personnel performing the activity, names of certain competition officials, and the projected end date of the competition. As noted above, agencies will have up to 135 calendar days to conduct a streamlined competition from the date it is publicly announced.

Second, the revised Circular ensures fairness by requiring that separate agency officials document cost estimates—one for agency performance and another for performance by either the private sector or a public reimbursable source. Cost calculations and comparisons must be documented on a standardized streamlined competition form (SLCF). *See* ¶ C.1. of Attachment B and ¶ A.12. of Attachment C.

Third, although the conversion differential typically used in a public-private competition does not apply to a streamlined competition, agencies must certify that the performance decision, as documented on the SLCF, is cost-effective. *See* Figure C3. of Attachment C. Agencies must make the certified SLCF available to the public upon request. *See* ¶ C.3.b. of Attachment B.

Fourth, agencies must track the results of competitions. In addition to reporting quarterly to OMB on the status of in-progress and completed competitions, agencies must monitor results, irrespective of the service provider, after the agency makes a performance decision. Agencies will be expected to implement a quality assurance surveillance plan, record the actual cost of performance, and collect performance information that may be considered in future competitions. *See* ¶ E.4. of Attachment B.

iv. *Creation of the MEO.* Several agency commenters stressed that effective public-private competition requires that agencies have the flexibility to adjust their in-house team's use of contract support when developing the MEO—*i.e.*, the staffing plan that will form the foundation of the agency's tender in a standard competition. The commenters noted that an existing mix of government personnel and contractor support may not be optimal given the agency's current needs and, on this basis, objected to language in the proposed Circular prohibiting the creation of new contracts as part of MEO development.

OMB seeks to vest agencies with the managerial authority they need to make sound programmatic decisions and has amended the Circular's coverage on standard competitions to give agencies the flexibility to create the best possible MEO. In developing their MEOs, agencies will be allowed to include contract support through new or potential contracts. However, agencies will not be permitted to include new MEO subcontracts if doing so would result in the direct conversion of work performed by government employees. *See* ¶ D 4.a.(1)(a). of Attachment B.

While agencies will have greater flexibility in standard competitions, they will be held fully accountable to the taxpayer for their actions. In addition to publicly announcing the start of a competition and performance decisions, the agency must perform and document a comprehensive calculation of costs on a standard competition form (SCF). As part of this effort, agencies must conduct price and cost realism analyses on all cost proposals and estimates, including the agency cost estimate. Directly interested parties may contest performance decisions (*see* below for additional discussion on contests). Upon resolution of a contest challenging a performance decision, or expiration of the time for filing such a contest, the certified SCF shall be available to the public upon request. Performance decisions under standard competitions, like those made under streamlined competitions, are subject to monitoring to ensure achievement of results. *See* ¶ E.4. of Attachment B.

b. Enhanced Inventories of Government Activities

An accurate inventory identifying an agency's commercial and inherently governmental activities is vital to a federal manager's ability to identify opportunities for which application of public-private competition is likely to yield the best return for the agency. For this reason, the revised Circular refines and expands guidance on the establishment of inventories. See Attachment A of the Circular. The revised Circular builds on existing statutory obligations set forth in the Federal Activities Inventory Reform (FAIR) Act (Pub. L. 105–270; 31 U.S.C. § 501 note) that require agencies to

prepare annual inventories of the commercial activities performed by their employees. These enhancements, many of which incorporate guidance contained in recent OMB memoranda, such as M–03–09 (''Year 2003 Inventories of Commercial and Inherently Governmental Activities''), include the following:

i. *More accurate picture of agencies' overall activities.* The revised Circular requires agencies to categorize all activities performed by government personnel as either commercial or inherently governmental. Agencies also must submit an annual inventory summary that reasonably equates to their authorized personnel requirements. Thus, in addition to identifying FAIR Act covered commercial activities and inherently governmental activities, agencies must summarize their other commercial inventory—*e.g.*, military personnel, foreign national employees, and ''other,'' such as activities performed at military depots and by government corporations. Similarly, agencies must include foreign national employees and military personnel employed by the agency in their summarized inherently governmental inventory. *See* ¶ A.5. of Attachment A.

ii. *Clarified rationales for government performance of a commercial activity.* The revised Circular requires agencies to choose one of six reason codes to explain why their personnel are performing a commercial activity. The reason codes are similar to, but more simplified than, the codes in the proposed Circular. In addition, the CSO must prepare a written justification if the agency concludes that the activity is eligible but not appropriate for private sector performance. *See* ¶ C.2. of Attachment A. Of particular note, the revised Circular, unlike the proposed Circular, authorizes challenges to an agency's application of reason codes. *See* ¶ D.2. of Attachment A. This step responds to calls, as reflected in the public comments, for greater transparency and accountability in the inventory process.

iii. *Consistent identification of inherently governmental activities.* Agencies will be required to submit annual inventories of their inherently governmental positions. As part of this effort, the proposed Circular sought to establish a presumption that all activities are commercial in nature unless an activity is justified as inherently governmental. A large number of commenters supported this change as a mechanism for ensuring that commercial activities are not camouflaged as inherently governmental. However, others strongly objected, asserting that the policy will pressure agencies to contract for activities that are intimately related to the public interest.

The revised Circular deletes this presumption to reassure the public that there is no intention to outsource inherently governmental activities. Inherently governmental activities must be performed by public employees, and the executive branch will continue to depend on its able workforce to execute these important responsibilities.

At the same time, the revised Circular retains a requirement from OFPP Policy Letter 92–1, Inherently Governmental Functions, and the proposed Circular that there be an exercise of substantial discretion in the application of government authority in order for an activity to be considered inherently governmental. *See* ¶ B.1.a. of Attachment A. Policy Letter 92–1 defines ''inherently governmental'' activities to include activities that require the ''exercise of discretion'' in applying Government authority. While the phrase ''substantial discretion'' does not appear in the definition, the policy letter provides additional guidance on the meaning of the phrase ''exercise of discretion.'' This guidance expressly states that ''inherently governmental functions necessarily involve the exercise of *substantial* discretion.''

Several commenters asserted that the proposed addition of the word ''substantial'' to the definition of ''inherently governmental'' in the revised Circular constitutes a major policy shift. OMB does not agree that this change signifies a major policy shift from Policy Letter 92–1. Although the absence of the adjective ''substantial'' from the definition in the policy letter may have caused some confusion in the past, OMB does not believe the clarification to require the exercise of substantial discretion will unnecessarily restrict the definition of inherently governmental, as some commenters argued. OMB has concluded that this clarification will enable agencies to make a cleaner delineation between those activities which are appropriately performed only by government personnel and those that are appropriately performed by either the public or private sector. To further assist agencies in identifying inherently governmental activities, the revised Circular provides a more concise definition of ''inherently governmental'' and rescinds the more complex description contained in OFPP Letter 92–1. *See* ¶ B.1.a. of Attachment A.

The revised Circular adopts the safeguards that were laid out in the proposed Circular to ensure that agency designations are rationally based. Specifically, the CSO must justify, in writing, all decisions to designate activities as inherently governmental. In this regard, OMB disagrees with one commenter's suggestion that the justification requirement imposes an unfair burden on agencies that designate activities as inherently governmental and notes that the revised Circular imposes a similar justification requirement on agencies who believe a commercial activity is unsuitable for competition. Also, the list of inherently governmental activities and the associated justifications will be made available for public review, with limited exception. *See* ¶¶ A.4. and B.1. of Attachment A. Finally, an agency's classification of an activity as inherently governmental may be challenged. *See* ¶ D.2. of Attachment A.

c. Better Planning

Many commenters made the point that agencies generally lack experience in planning for and conducting public-private competition. They feared that the results of competition will fall short of expectations—especially in light of the time constraints under which competitions must be conducted—unless agencies make more concerted efforts to properly plan for them.

OMB strongly agrees that effective agency planning is a critical prerequisite for sound sourcing decisions. The revised Circular refines and bolsters the coverage in the proposed Circular on preliminary planning. *See* ¶ A. of Attachment B. This coverage applies to the two types of competitions authorized by the revised Circular: standard competitions and streamlined competitions.

Before announcing the commencement of a streamlined or standard competition, agencies must complete a series of actions. These actions include:

- Determining the scope (*i.e.*, the activities and positions to be competed);
- Conducting preliminary research to determine the appropriate grouping of activities as business units (*e.g.*, consistent with market and industry structures);
- Assessing the availability of workload data, quantifiable outputs of activities, and agency or industry performance standards; and
- Determining the baseline cost of the activity as performed by the incumbent service provider.

Agencies also must appoint competition officials. For standard competitions, these officials will include:

• An agency tender official (ATO) with decision-making authority who is responsible for the agency tender (*i.e.*, the agency management plan submitted in response to a solicitation for a standard competition) and represents the agency tender during source selection;

• A contracting officer (CO) who is responsible for issuance of the solicitation and the source selection evaluation and participates on the team that develops the performance work statement (PWS);

• A PWS team leader who is responsible for developing the PWS and quality assurance surveillance plan, determines if the government will furnish property, and assists the CO with the solicitation;

• A human resource advisor (HRA) who is responsible for assisting the ATO in human resource-related matters related to the agency tender; and

• A source selection authority (SSA) who is responsible for source selection.

While the revised Circular imposes timeframes to ensure competitions are completed within a reasonable period, these periods will not begin until the agency completes its planning and announces the competition. *See* ¶ B. of Attachment B. This approach will ensure competitions are adequately and properly planned.

The revised Circular, like the proposed Circular, recognizes the talents of the federal workforce, the conditions under which it operates, and the importance of providing the workforce with adequate training and technical support during the competition process to ensure they are able to compete effectively. In this regard, the revised Circular requires that the ATO have access to available resources (*e.g.*, skilled manpower, funding) necessary to develop a competitive agency tender. *See* ¶ A.8.a. of Attachment B. In addition, if material deficiencies are found in an agency tender (*i.e.*, the agency management plan submitted to respond to a solicitation for a standard competition), OMB will expect the agency's CSO to take all necessary steps to identify the source of the problem and allow the ATO the opportunity to correct the deficiency.

d. More Manageable and Accommodating Source Selection Processes

As noted above, and discussed more extensively in the preamble to the proposed Circular, the competition processes provided for in the prior Circular have been criticized as time consuming, complex, and difficult to manage. Many also believe that the prior Circular does not sufficiently accommodate agency needs to consider quality and innovation, especially where these needs may require complex and inter-related services.

The revised Circular's guidance on source selections is designed to be more manageable, more reliant on well-established FAR principles, and more accommodating than that which was developed over the years for the performance of cost comparisons—*i.e.*, the traditional cost-centric process for conducting public-private competitions.

The revised Circular, like the proposed Circular, provides several alternative procedures for conducting source selections, two of which give agencies leeway to take non-cost factors into account. Specifically:

• An agency may use sealed bidding where the award will be made strictly on the basis of price and price-related factors and the agency will not need to negotiate with sources. *See* ¶ D.5.a. of Attachment B.

• An agency may conduct a lowest price technically acceptable source selection where the performance decision is based on the lowest cost offer of all the offers that have been determined to be technically acceptable. This process permits exchanges between the parties. *See* ¶ D.5.b.(1). of Attachment B.

• An agency may conduct a phased evaluation source selection process to have the flexibility of considering alternative performance levels that sources may wish to propose. During the first phase, only technical factors are considered, and all prospective providers (the agency, public reimbursable sources, and private sector offerors) may propose performance standards different from those specified in the solicitation. If the agency determines that a proposed alternative performance standard is appropriate and within the agency's current budget, the agency must issue a formal amendment to the solicitation and request revised submissions. In the second phase, the SSA makes a performance decision after performing price and cost realism analyses to compare offers and tenders that were determined to be technically acceptable at the conclusion of the first phase. *See* ¶ D.5.b.(2). of Attachment B.

• An agency may conduct a tradeoff source selection process with cost-technical tradeoffs similar to those authorized by FAR Part 15, if non-cost factors are likely to play an important role in the selection decision. Like the FAR Part 15 process, all prospective providers (private sector offers, public reimbursable sources, and the agency) may propose different performance standards than stated in the solicitation. The contracting officer is required to determine if any desired tradeoffs are affordable and document the rationale for these tradeoffs. The Circular limits use of tradeoffs to: (1) Information technology (IT) activities, (2) contracted commercial activities, (3) new requirements, (4) segregable expansions, or (5) activities approved by the CSO before public announcement, with notification to OMB. *See* ¶ D.5.b.(3). of Attachment B.

While the phased evaluation and tradeoff source selection give agencies greater leeway to take non-cost factors into account, OMB anticipates that cost will oftentimes be the most important factor when these processes are used. Either way, the Circular will continue to require the meaningful consideration of cost as a factor in all public-private competitions. For example, in a tradeoff source selection, the specific weight given to cost or price must be at least equal to all other evaluation factors combined unless quantifiable performance measures can be used to assess value and can be independently evaluated. (The solicitation for a tradeoff source selection must identify the specific weight given evaluation factors and sub-factors, including cost or price.) *See* ¶ D.3.a.(3)(b) of Attachment B.

In addition, the revised Circular will continue to require the calculation of a conversion differential for all source selections under standard competitions. The conversion differential is a cost that is the lesser of 10 percent of the MEO's personnel-related costs or $10 million over all the performance periods stated in the solicitation. The conversion differential is added to the cost of performance by a non-incumbent source. If the incumbent provider is a private sector or public reimbursable source, the conversion differential is added to the cost of agency performance. If the agency is the incumbent provider, the conversion differential is added to the cost of private sector or public reimbursable performance. *See* ¶ D.5.c.(4)(c). of Attachment B and ¶ A.5. of Attachment C. For the tradeoff source selection, the conversion differential is added to the cost for a non-incumbent source. Consideration of the conversion differential in the tradeoff process is not intended to discourage agencies from selecting other than the lowest cost provider. Rather, application of the conversion differential is intended to ensure that cost is given meaningful consideration in trading off cost and

non-cost considerations in the final performance decision.

Numerous comments addressed the proposed source selection processes. Most focused either on the tradeoff process (referred to as the ''integrated evaluation process'' in the proposed Circular) or the application of the Circular to acquisitions of architect and engineering (A&E) services.

i. *Expanded use of tradeoffs.* Reactions to the proposed coverage on tradeoffs were mixed. Some commenters complained that tradeoffs were inappropriate for competitive sourcing. They asserted that the subjective nature of tradeoffs would invite gaming that, in turn, would discourage robust participation in public-private competitions. Others, by contrast, expressed support for the new option. They pointed out that a more integrated FAR-type competition process, with appropriate elements of Circular A–76, was recommended by the Commercial Activities Panel. (The Panel, which included experts from both the public and private sectors—including Congress, the Executive Branch, industry, and the Federal employee unions—was established by section 832 of the Fiscal Year 2002 Defense Authorization Act to study competitive sourcing. The Panel issued a report with recommendations in May 2002.) Some commenters strongly encouraged OMB to expand use of the tradeoff process and the procedures of FAR Part 15 to activities other than IT to enable agencies to gain broader experiences and insight.

OMB does not agree with those who argue that tradeoffs are inappropriate for public-private competitions. OMB believes that agencies need greater ability to consider non-cost factors if they are to make strategic decisions for the agency. On the other hand, OMB understands that the tradeoff process may not be appropriate in all instances, especially given the special considerations that must be taken into account with any public-private competition, including those involving tradeoffs. *See* ¶ D.5. of Attachment B. OMB therefore has concluded that the parameters described in the proposed Circular for using tradeoffs are reasonable and has adopted these parameters in the revised Circular. As noted above, these parameters allow the CSO to consider appropriate application of the tradeoff process for non-IT activities on a case-by-case basis.

ii. *Application of the Circular to A&E services.* A number of commenters argued that the procedures in the Circular conflict with statutory requirements in the Brooks Act, 40 U.S.C. 541, *et seq.*, which prescribe a specific process for evaluating quality and cost in proposals for A&E. Some suggested that OMB revise the Circular to reflect the procedures in FAR Subpart 36.6, which implements the requirements of the Brooks Act. Others suggested that direct conversions be authorized to address these needs.

OMB appreciates that the processes statutorily prescribed for acquiring A&E services are different from those in FAR Parts 14 and 15, which are used for most types of purchases other than for A&E services. OMB does not believe that this difference should automatically render the policies and management responsibilities of the Circular inapplicable to A&E services. No clearly commercial activity, whether A&E services or any other type of service, should be sealed off from the forces of competition. However, the revised Circular acknowledges that there may be a need for use of part 36 procedures. *See* ¶ D.3.a.(2). of Attachment B. OMB believes that additional thought is required regarding the specifics of how the revised Circular would be applied to A&E services and the type of deviation that might be needed. Therefore, OMB encourages agencies that have identified A&E services in their competition plans to consult with OFPP as they prepare to undertake competitions and request deviations as appropriate.

e. Right of First Refusal

The proposed Circular would have assigned to the HRA the responsibility for determining, in conjunction with the CO, compliance with right-of-first-refusal requirements when the agency is the incumbent service provider and a performance decision favors private sector performance. One commenter, in particular, strongly objected to this augmentation of responsibilities, asserting that it would effectively force a government official to make hiring decisions for the selected contractor. OMB has concluded that this responsibility should not be assigned to the HRA and the Circular has been revised accordingly. As a result, the contractor will determine who is qualified to work on the contract.

f. Use of Innovation

OMB believes the new standard and streamlined competition processes should effectively accommodate agency needs for the vast majority of public-private competitions conducted under the Circular. At the same time, OMB recognizes both the need for flexibility to address unique circumstances and the value in experimentation to improve business management processes as agencies gain experience with the Circular and greater insight into how its principles are best achieved. For this reason, the revised Circular provides a process by which agencies, with OMB's prior written approval, may deviate from the processes prescribed by the Circular. *See* ¶ 5.c. of the revised Circular. OMB will carefully consider agency requests for deviations to determine if they are justified and in the government's best interest, taking into consideration the special circumstances that surround a public-private competition, especially those that involve an agency tender. The deviation process may also be considered for pursuit of alternatives to public-private competitions in appropriate circumstances, such as public-private partnerships, public-public partnerships, and high performing organizations.

g. Focused Implementation

After considerable deliberation, OMB decided to eliminate the proposed coverage on fee-for-service interagency agreements with public reimbursable sources (referred to in the proposed Circular as interservice support agreements, or ISSAs). The coverage was set forth at Attachment D of the proposed Circular.

OMB believes a more directed management focus, in the short term, should enable agencies to more quickly acclimate themselves to the Circular's improved processes. OMB anticipates that faster agency acclimation to standard and streamlined competitions will translate into successful use of competition for the activities agencies have identified in their competition plans, which, in most cases, are internal activities that have traditionally been shielded from the pressures of the marketplace.

OMB remains committed to finding appropriate incentives for all public and private sources to perform at their best when providing services to the taxpayer. OMB hopes that faster acclimation to the revised Circular, and the institutionalization of competitive sourcing generally, will lay a firm foundation for expanded application of public-private competition to agency-to-agency arrangements over time.

2. Ensuring Fairness, Integrity, and Transparency

The revised Circular seeks to improve public trust in sourcing decisions by incorporating appropriate mechanisms of transparency, fairness, and integrity. These mechanisms are critical for ensuring the type of robust participation that will effectively bring market

pressures to bear, as well as the type of even-handed environment that will result in performance by the best source. Mechanisms include the following:

a. Greater Uniformity in the Application of Basic Requirements

Various provisions in the revised Circular are designed to create greater equality in the application of requirements to agencies and private sector offerors. For example:

- The ATO must respond to a solicitation within the same timeframes required of private sector offerors. An agency may extend this timeframe for all offerors if it is in the best interest of the government. *See* ¶ D.4.a.(2). of Attachment B.
- An agency tender may be excluded from a standard competition without cancellation of the competition, if the SSA identifies a material deficiency and the CSO determines that the material deficiency cannot be corrected with a reasonable commitment of resources. *See* ¶ D.5.c.(3). of Attachment B.
- Once work has been competed under the Circular, agencies must recompete work being performed by government personnel or public reimbursable sources in accordance with the same time limitations imposed by the FAR on contracts with the private sector, unless the CSO grants a specific exemption for a high performing organization. *See* ¶ E.5.b. of Attachment B.
- Before exercising options for additional performance of work that has been competed under the Circular, agencies must determine that performance by the incumbent provider (MEO, public reimbursable source, or private sector provider) meets the requirements of the solicitation and that continued performance is advantageous to the agency. *See* ¶ E.5.a. of Attachment B.

Some commenters felt these changes will undo special considerations in the existing circular that ensure a level playing field between the sectors, especially when the government is the provider. By contrast, others suggested that procedural differences in the handling of agency tenders and private sector offers are still too great, even with the changes described above. For example, some asserted that the latitude given to the government to make a late tender submission is broader than that afforded to the private sector and creates an unfair advantage for the government.

To build confidence in the competitive sourcing process, OMB has minimized differences, wherever possible. At the same time, legitimate special considerations that need to be addressed to ensure a level playing field have been taken into account. For example, when a material deficiency is discovered in an agency tender and a question arises as to whether the deficiency can be corrected, the agency must take all reasonable steps to enable corrective action. OMB expects the CSO to give consideration to all possibilities for addressing material deficiencies that cannot be easily corrected. Considerations include the commitment of additional resources and, if necessary, a request to OMB to deviate from the Circular by extending the time for completing a competition—assuming such extension is within reason and the CSO can demonstrate the deficiency will be corrected.

b. Avoiding the Appearance of Conflicts of Interests

The revised Circular establishes new rules to avoid the appearance of a conflict of interest. In particular, the revised Circular separates the PWS team formed to write the PWS from the MEO team formed to develop the agency tender. In addition, the MEO team, directly affected personnel and their representatives, and any individual with knowledge of the MEO or agency cost estimate in the agency tender are not allowed to be advisors to, or members of, the source selection evaluation board. *See* ¶ D.2. of Attachment B.

c. Public Release of Tenders

The revised Circular adds a new provision requiring the release of the agency tender, public reimbursable tenders, and the certified SCF upon the resolution of any contest challenging the performance decision or the expiration of the time for filing such a contest. *See* ¶ D.6.e. of Attachment B. The SCF documents all costs calculated in the competition to make a performance decision. Several agencies asserted that this information should be treated as proprietary and not released—even after a performance decision—just as a private sector offer would not be released under similar circumstances. OMB believes that a tender should not be hidden from the taxpayer to whom we are ultimately accountable. At the same time, the Circular makes clear that proprietary information of private sector providers of subcontracts included in agency or public reimbursable tenders shall not be released.

d. Fairer and More Accurate Cost Estimates

As a general matter, Attachment C is intended to ensure that public-private competitions reflect the full cost of performance by the government so that competitions are fair. Agencies will be expected to use the costing procedures in Attachment C combined with the COMPARE costing software to calculate and document the costs on the SCF or SLCF for a streamlined or a standard competition. Agencies may not use agency budgetary estimates to develop government cost estimates. *See* ¶ 4.h. of the revised Circular.

The revised Circular also makes adjustments to the handling of certain costs to eliminate unfair results. For example, based on contractor recommendations in the public comments, the revised Circular prohibits the government from including the cost of contractor security clearances as a one-time conversion cost that is added to the contractor's price. By removing this cost from the comparison, a more level playing field is created between the government and the private sector.

e. Improved Process for Contests

One agency commenter with significant experience in using A–76 recommended that the revised Circular rely on the agency protest process set forth in the FAR rather than perpetuating a separate administrative process. The commenter complained that the Circular's administrative process adds little value beyond that offered by relying upon the FAR.

The revised Circular replaces the prior Circular's administrative appeals process with the processes in the FAR at 33.103. As a result, challenges by directly interested parties and resolution of such challenges by the agency are governed by the procedures in FAR 33.103. A directly interested party may challenge any of the following actions taken in connection with a standard competition: (1) A solicitation; (2) the cancellation of a solicitation; (3) a determination to exclude a tender or offer from a standard competition; (4) a performance decision, including, but not limited to, compliance with the costing provisions of the Circular and other elements in an agency's evaluation of offers and tenders; or (5) a termination or cancellation of a contract or letter of obligation if the challenge contains an allegation that the termination or cancellation is based in whole or in part on improprieties concerning the performance decision. No party may contest a streamlined competition. However, agencies will be held accountable for performance decisions made in connection with such competitions, as addressed in ¶ E. of Attachment B.

Several commenters complained the definition of ''interested party'' in the proposed Circular was too narrow because it limited a public offeror's access to administrative relief only through the ATO. OMB seeks to ensure equal and fair access to challenge processes and has revised the Circular to broaden the definition of interested party to permit administrative challenge by a single representative appointed by a majority of directly affected employees in addition to the ATO. *See* the definition of directly interested party in Attachment D.

3. Strengthening Accountability for Results

The ultimate success of Circular A–76 in delivering results for the taxpayer requires that public or private sources make good on their promises to the government. To this end, the revised Circular incorporates various accountability protections. For example, as discussed in ¶ C.1.a.ii. of this preamble, competition timeframes have been incorporated into the Circular, among other things, to instill greater confidence by all participants that agencies are committed to the timely and competitive selection of the best provider. Other accountability mechanisms include the following:

a. Centralized Oversight Responsibility

Agencies must establish a program office responsible for the daily implementation and enforcement of the Circular. Improved oversight will serve to enhance communications, facilitate sharing of lessons learned, and significantly improve overall compliance with the Circular. *See* ¶ 4.g. of the revised Circular.

b. Letters of Obligation

For a performance decision favoring the agency, the CO will be required to establish an MEO letter of obligation with an official responsible for performance of the MEO. The CO shall incorporate appropriate portions of the solicitation and the agency tender into the MEO letter of obligation and distribute the letter to appropriate individuals including the ATO. (For a performance decision favoring a public reimbursable source, the CO will be required to develop a fee-for-service agreement with the public reimbursable source.)

c. Improved Post Competition Oversight

Agencies must track agency execution of streamlined and standard competitions, using a government-wide management information system. Information to be tracked by this system will include, among other things: Baseline costs, start date, number of directly affected employees performing the activity, solicitation information, type of acquisition and source selection, decisions for tradeoff source selections, number of private sector offers received, performance date and decision, socio-economic information, decisions for tradeoff source selections, and number of directly affected employees that are involuntarily separated. Agencies must review their data to make process improvements, identify streamlining measures, determine trends, and identify savings. Tracking is required irrespective of whether the service provider is from the public or private sector. This system will help to ensure public providers are subjected to the same oversight that private providers routinely face.

Finally, agencies must post lessons learned and best practices on SHARE A–76! *See* ¶ 4.g. of the revised Circular. In this way, current experiences can routinely be used to inform and improve competition practices and decision making.

Mitchell E. Daniels, Jr.,

Director.

[FR Doc. 03–13457 Filed 5–28–03; 8:45 am]

BILLING CODE 3110–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration on the American Stock Exchange LLC (Anworth Mortgage Asset Corporation, Common Stock, $.01 par Value) File No. 1–13709

May 22, 2003.

Anworth Mortgage Asset Corporation, a Maryland corporation (''Issuer''), has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to section 12(d) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 12d2–2(d) thereunder,[2] to withdraw its Common Stock, $.01 par value (''Security''), from listing and registration on the American Stock Exchange LLC (''Amex'' or ''Exchange'').

The Issuer stated in its application that it has met the requirements of Amex Rule l8 by complying with all applicable laws in the State of Maryland, in which it is incorporated, and with the Amex's rules governing an issuer's voluntary withdrawal of a security from listing and registration.

The Issuer states that it is taking such action for the following reasons: the Issuer recently listed its Security on the New York Stock Exchange (''NYSE'') stating that doing so should be beneficial to the stockholders, will provide greater liquidity, and will increase the Company's exposure to the European markets.

The Issuer's application relates solely to the withdrawal of the Securities from listing on the Amex and from registration under section 12(b) of the Act[3] shall not affect its obligation to be registered under section 12(g) of the Act.[4]

Any interested person may, on or before June 17, 2003, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Jonathan G. Katz,

Secretary.

[FR Doc. 03–13367 Filed 5–28–03; 8:45 am]

BILLING CODE 8010–01–P

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 15 U.S.C. 78*l*(g).

[5] 17 CFR 200.30–3(a)(1).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 68 FR 28302, May 23, 2003.

STATUS: Closed Meeting/Open Meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Tuesday, May 27, 2003 at 2 p.m. and Wednesday, May 28, 2003 at 10 a.m.

CHANGE IN THE MEETINGS: Date and Time Changes.

The Closed Meeting scheduled for Tuesday, May 27, 2003 at 2 p.m., has been changed to Wednesday, May 28, 2003 at 3:30 p.m.

The Open Meeting scheduled for Wednesday, May 28, 2003 at 10 a.m., has been changed to Tuesday, May 27, 2003 at 2 p.m.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 942–7070.

Dated: May 23, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–13495 Filed 5–23–03; 4:26 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47899; File No. SR–DTC–2003–06]

Self-Regulatory Organizations; the Depository Trust Company; Notice of Filing of Proposed Rule Change To Restrict the Next-Day Matched Reclamation Process

May 21, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on April 7, 2003, The Depository Trust Company (''DTC'') 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 primarily by DTC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

DTC is seeking to restrict the ability of participants to effect reclamations to reverse completed Deliver Order (''DO'') and Payment Order (''PO'') transactions processed on the previous business day.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC 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. DTC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

DTC's current reclamation procedures allow participants to submit reclamations to reverse completed DO and PO transactions. When reclamation instructions are received, DTC currently attempts to match the reclaim with a completed original transaction processed on the current day (''same-day reclaims'') or on the preceding business day (''next-day reclaims''). Reclamations that are not matched to original deliveries are considered unmatched reclaims and are subject to the same rules and controls as original transactions. Reclamations that are matched to original deliveries are considered matched reclaims and are permitted to bypass the Receiver Authorized Delivery (''RAD'') system and override DTC's risk management controls if they are DOs less than $15 million or POs less than $1 million.[3] In addition, matched reclamations can be processed in the exclusive reclaim period (3:20 p.m. to 3:30 p.m.) and cannot be re-reclaimed by the receiver.

Reclamations in general and next-day reclamations in particular impair the finality of settlement and prolong the period during which delivering participants and DTC are at risk. To minimize this exposure, DTC plans to eliminate the next-day matched reclamation process. Under its proposed procedures, DTC would continue to accept reclamation instructions and link those reclaim transactions to original transactions. However, only reclamation transactions that are linked to original transactions processed the same processing day would be considered matched. Only these matched reclaim transactions would be permitted to bypass RAD and DTC's risk management controls. In addition, only these matched reclaim transactions could be submitted in the exclusive reclaim period and would be blocked from subsequent re-reclamation by the original deliverer.

Reclamation transactions that are linked to original transactions processed prior to the current processing day would be processed in the same manner as other deliveries. That is, they would not bypass RAD or DTC's risk management controls. These linked reclamations would have to be submitted during normal input times and would not be allowed in the exclusive reclaim period. Furthermore, a participant receiving a linked reclamation that it believes is inappropriate would be able to re-reclaim that transaction. To allow participants to continue automatically tracking transaction status changes, however, both matched and linked reclaim output will contain the Relative Block Number of both the reclamation and the original transaction.

DTC plans to implement the enhancements to the reclamation process in phases. Beginning July 17, 2003, subject to Commission approval, DTC will eliminate the next-day matched reclaim process for money market instruments (''MMIs''). After that date, MMI reclaim transactions that cannot be matched to original transactions processed on the same business day will be processed in the same manner as other deliveries. DTC plans to eliminate the next-day matched reclaim capability for all other securities late in 2003 or early in 2004. At that time, DTC also proposes to begin linking reclamation transactions with original transactions processed in the preceding 60 days.

DTC believes that the proposed rule change is consistent with the requirements of section 17A of the Act[4] and the rules and regulations thereunder applicable to DTC. By restricting the next-day matched reclamation process, the proposed rule change should remove impediments to the finality of the settlement process and should shorten the period during which delivering participants and DTC are at risk. As a result, the proposed rule change should promote the prompt and accurate clearance and settlement of securities transactions.

(B) Self-Regulatory Organization's Statement on Burden on Competition

DTC perceives no impact on competition by reason of the proposed rule change.

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by DTC.

[3] RAD is a control mechanism that allows participants to review transactions prior to completion of processing and that limits participants' exposure from misdirected or erroneously entered deliveries or payment orders. The override of DTC's risk management controls is designed to address industry concern that the receiver not be ''stuck'' with a delivery it does not know because of the depository's risk management controls.

[4] 15 U.S.C. 78q–1.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

DTC has discussed this proposed rule change in its current form with various industry groups and distributed Important Notice #4639 (February 26, 2003) to participants soliciting their comments. No comments were received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five 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 ninety 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. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Comments may also be submitted electronically at the following e-mail address: *rule-comments@sec.gov.* All comment letters should refer to File No. SR–DTC–2003–06. This file number should be included on the subject line if e-mail is used. To help us process and review comments more efficiently, comments should be sent in hardcopy or by e-mail but not by both methods. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of DTC.

All submissions should refer to File No. SR–DTC–2003–06 and should be submitted by June 19, 2003.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[5]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–13449 Filed 5–28–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47897; File No. SR–NASD–2003–48]

Self-Regulatory Organizations; Order Granting Approval to Proposed Rule Change by the National Association of Securities Dealers, Inc. To Modify the Display Charge Associated With the Use of the Nasdaq Workstation II Service by Persons That Are Not NASD Members

May 21, 2003.

On March 21, 2003, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), through its subsidiary The Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and rule 19b–4 thereunder,[2] a proposed rule change to modify the display charge associated with the use of the Nasdaq Workstation II Service (''Service'') by persons that are not NASD Members. Specifically, the proposal would provide a discount on each additional Service logon to subscribers with more than 150 logons.[3] The proposed rule change was published for comment in the **Federal Register** on April 21, 2003.[4] The Commission received no comments on the proposal.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association[5] and, in particular, the requirements of section 15A of the Act[6] and the rules and regulations thereunder. The Commission finds specifically that the proposal is consistent with the requirements of section 15A(b)(5) of the Act,[7] because it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system that NASD operates. Nasdaq has represented that it is proposing to modify the display charge to reflect the economies of scale realized when providing a subscriber with a large number of logons. Further, Nasdaq has already implemented a similar fee schedule for members.[8] The Commission believes that the proposed fee discount on each additional Service logon to subscribers with more than 150 logons should assist in reducing costs incurred by all market participants using Nasdaq's systems and services.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[9] that the proposed rule change (File No. SR–NASD–2003–48) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–13445 Filed 5–28–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47906; File No. SR–NASD–2003–62]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change, and Amendment No. 1 Thereto, by National Association of Securities Dealers, Inc. To Allow Internet Access to the Primex Auction System and To Specify the Charges for Such Access

May 22, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and rule 19b–4 thereunder,[2] notice is hereby given that on March 31, 2003, the National Association of Securities Dealers, Inc. (''NASD''), through its subsidiary, the Nasdaq Stock

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[5] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission notes that Nasdaq also submitted a separate proposed rule change, pursuant to section 19b(3)(A) of the Act, 15 U.S.C. 78s(b)(3)(A), to modify this charge for NASD members. *See* Securities Exchange Act Release No. 47637 (April 7, 2003), 68 FR 17849 (April 11, 2003) (File No. SR–NASD–2003–47).

[4] *See* Securities Exchange Act Release No. 47679 (April 15, 2003), 68 FR 19593.

[5] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78*o*–3.

[7] 15 U.S.C. 78*o*–3(b)(5).

[8] *See supra* note 3.

[9] 15 U.S.C. 78s(b)(2).

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in items I, II, and III below, which items have been prepared by the Nasdaq. On May 16, 2003, the Nasdaq filed Amendment No. 1 to the proposal.[3] 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 Nasdaq proposes to amend NASD rules 5012 and 7010(r) to enable access to the Primex Auction System (''Primex'') via the Internet and to specify the charges for such access.

The text of the proposed rule change, as amended, is below. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

Rule 5012. Access

(a) No change.

(b) No change.

(c) The Application may be made available [through Nasdaq-provided network(s) via]:

(1) *through Nasdaq-provided network(s) via* Primex Auction System Workstation Service;

(2) *through Nasdaq-provided network(s) via* an Application Programming Interface (''API''); [or]

(3) *through Nasdaq-provided network(s) via* a FIX protocol interface[. Certain functionality of the Application also may be made available via Computer to Computer Interface (CTCI).]*; or*

(4) *over the Internet, using Nasdaq-provided user interface. Certain functionality of the Application may be made available through Nasdaq-provided network(s) via Computer to Computer Interface (CTCI).*

Rule 7010(r). Nasdaq Application of the Primex Auction System

(1) No change.

(2) Monthly Access Fees

SOFTWARE

Workstation license or unique logon	Per workstation logon
Stations/logons 1–10	$200

SOFTWARE—Continued

Workstation license or unique logon	Per workstation logon
Stations/logons 11–25	$100
Stations/logons 26 and above	$50

Proprietary interface license	Per license
API specification	$500
FIX (customized protocol)	$500

NETWORK

Dedicated line	Per line
256K	$1,781
64K with non-guaranteed 256K burst capacity	$1,564
56K	$712
Installation/Uninstall	[1] $1,000
Internet Access	
Logons 1–10 (per firm)	*$50*
Logons 11 and up (per firm)	*$25*

[1] Per Nasdaq Staff site visit.

* * * * *

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 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

a. Overview

Currently, any firm wishing to connect to Primex and take full advantage of its functionality must purchase an Auction Control Box (''ACB'') server and maintain a dedicated T1 circuit between its premises and the Primex system on Nasdaq's premises. To provide firms with a lower cost full-access alternative, Nasdaq intends to introduce the option of accessing Primex through the Internet. Interested firms would be able to connect to Primex via their existing Internet link and would not need either to purchase an ACB server or maintain a separate dedicated circuit between their own premises and Primex. The Internet access option is intended both to attract new participants to Primex and to provide additional flexibility of access for existing participants.

b. Internet Connectivity and Resulting Cost Savings

A participant wishing to connect to Primex over the Internet would need to obtain Internet access from an Internet Service Provider (''ISP'') and a telecommunications circuit linking the participant's premises with the ISP's point of presence from a local telecommunications provider (''Telco''). Typically, a participant would use the same Telco circuit and ISP port for all of its Internet connectivity needs (including, but not limited to, connectivity with Primex). Consequently, the required bandwidth of the needed ISP port and Telco circuit, and the corresponding costs, would be dictated by each participant's specific overall Internet usage requirements, which includes applications unrelated to Primex (*e.g.*, email, web access, etc.). However, Nasdaq expects that, at any given level of Primex usage, the cost of the portion of the total bandwidth of the ISP port and of the Telco circuit actually used for Primex access would be substantially lower than the cost of a dedicated line that would otherwise be required to link the participant's premises with the Primex server. The monthly logon fees that Nasdaq itself proposes to charge for Internet access to the Primex are also substantially lower than the current logon fees for Primex access via a dedicated line.

c. The Look and Feel Is Unchanged

Nasdaq represents that Primex users that choose to access Primex over the Internet will generally enjoy the same ''look and feel'' experience as the users of the existing dedicated circuit mode of access. Nasdaq will provide to interested users compact discs with the user interface software required for Internet access. Before a connection with the Primex server can be established, the user would need to install the provided interface software and then run it. The interface software would, in turn, prompt the user for certain identifying information (ID and password). Once the identifying information is entered correctly, a full connection is established, and the user sees essentially the same screen display as he/she would see when using a dedicated connection. All other screen displays will also be essentially the same.

[3] *See* letter from Alex Kogan, Associate General Counsel, Nasdaq to Katherine A. England, Assistant Director, Division of Market Regulation, Commission, dated May 15, 2003 (''Amendment No. 1''). In Amendment No. 1, the Nasdaq submitted a new Form 19b–4, which replaced the original filing in its entirety.

d. Same Functionality

Nasdaq represents that Primex users that choose to access Primex over the Internet will also have access to the same functionality as they would over a dedicated circuit. In particular, Internet users will be able to enter orders, enter predefined relative indications (''PRIs''), respond to auctions, view orders, executions and PRIs, and withdraw PRIs. Once the Internet user's identity and authority to access the system is established, he/she should be able to take full advantage of Primex, while benefiting from the lower cost of the connection.

e. Security

A firm that wishes to enable its employees to access Primex over the Internet will need to coordinate requests for user authorization with Nasdaq. Such a firm's designated security administrator will provide Nasdaq with written authorization and required enrollment information. Once Nasdaq has the needed information, it will enroll the user for Internet access to Primex and provide to the user, by a secure method, certain information required to enable such access. The firm's security administrator will also be expected to give Nasdaq timely notification to disenroll any previously enrolled user who is no longer eligible for (or no longer needs) Internet access to Primex.

Nasdaq may, from time to time, change the enrollment/disenrollment requirements, methods and procedures and will advise the participating firms accordingly. Nasdaq will work with participating firms' designated security administrators to help implement user enrollment/disenrollment and to assist with the security procedures related to accessing Primex over the Internet.[4]

f. Capacity and Connection Quality

Nasdaq believes that, in its current configuration, Primex will at all times have adequate capacity to handle the expected volume of Internet connections and to accommodate a robust growth in volume with no degradation in the quality of service. Primex currently has the capacity to handle up to five times as many simultaneous connections over the Internet as Nasdaq's initial peak time estimates suggest may actually occur. Nasdaq is able to add further capacity, so as to meet any reasonably possible surge in demand, within a matter of days.

The quality of any user's connection to Primex will, obviously, also depend on the quality of that user's Internet connection, including the nature and adequacy of the connection to the user's chosen ISP, the robustness of that ISP's network and interconnections, and the robustness of the interconnected networks. Nasdaq expects that the degree to which Primex participants choose to rely on Internet access would be consistent with the quality of Internet service such participants are able to obtain.

2. Statutory Basis

Nasdaq believes that the proposed rule change, as amended, is consistent with the provisions of section 15A of the Act,[5] in general and with section 15A(b)(5) of the Act,[6] in particular, which requires that the rules of the NASD provide for equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the NASD operates or controls. The proposed modification to provide a lower-cost option for accessing the Primex Auction System supports efficient use of existing systems and ensures that the associated costs are allocated equitably. Nasdaq believes that the proposed fees, which are lower than the current fees for accessing the Primex Auction System, are reasonable and equitable.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change, as amended, will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the NASD consents, the Commission will:

(A) By order approve such proposed rule change, as amended, or

(B) Institute proceedings to determine whether the proposed rule change, as amended, 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, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room.

Copies of such filings will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR–NASD–2003–62 and should be submitted by June 19, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–13447 Filed 5–28–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47909; File No. SR–NASD–2003–82]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. To Extend a Pilot Amendment to NASD Rule 4120 Regarding Nasdaq's Authority To Initiate and Continue Trading Halts

May 22, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934

[4] Nasdaq will keep the Commission staff apprised of any modifications in or updates to Primex user enrollment-related procedures when such modifications or updates substantially affect the security of Internet access to Primex.

[5] 15 U.S.C. 78*o*–3.

[6] 15 U.S.C. 78*o*–3(b)(5).

[7] 17 CFR 200.30–3(a)(12).

(''Act''),[1] and rule 19b–4 thereunder,[2] notice is hereby given that on May 12, 2003, the National Association of Securities Dealers, Inc. (''NASD''), through its subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in items I and II below, which items have been prepared by Nasdaq. Nasdaq filed the proposal pursuant to section 19(b)(3)(A) of the Act,[3] and rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission.[5] 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

Nasdaq proposes to extend a pilot amendment to NASD rule 4120, which clarified Nasdaq's authority to initiate and continue trading halts in circumstances where Nasdaq believes that extraordinary market activity in a security listed on Nasdaq may be caused by the misuse or malfunction of an electronic quotation, communication, reporting, or execution system operated by, or linked to, Nasdaq. The purpose of this filing is to extend the pilot until August 15, 2003. Accordingly, there is no new proposed rule language. Nasdaq is making no substantive changes to the pilot, other than to extend its operation through August 15, 2003.

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

On May 11, 2001, Nasdaq filed with the Commission a proposed rule change to clarify Nasdaq's authority to initiate and continue trading halts in circumstances where Nasdaq believes that extraordinary market activity in a security listed on Nasdaq may be caused by the misuse or malfunction of an electronic quotation, communication, reporting, or execution system operated by, or linked to, Nasdaq.[6] On July 27, 2001, Nasdaq filed Amendment No. 1 to the proposed rule change, which requested that the Commission approve the proposed rule change on a three-month pilot basis expiring on October 27, 2001.[7] Also on July 27, 2001, the Commission approved the proposed rule change and Amendment No. 1.[8] Since that time, the pilot period for the rule has been extended on several occasions.[9]

As a result of the decentralized and electronic nature of the market operated by Nasdaq, the price and volume of transactions in a Nasdaq-listed security may be affected by the misuse or malfunction of electronic systems, including systems that are linked to, but not operated by, Nasdaq. In circumstances where misuse or malfunction results in extraordinary market activity, Nasdaq believes that it may be appropriate to halt trading in an affected security until the system problem can be rectified. In the period during which the rule change has been in effect, Nasdaq has not had occasion to initiate a trading halt under the rule. Nevertheless, Nasdaq believes that the rule is an important component of its authority to maintain the fairness and orderly structure of the Nasdaq market. Accordingly, Nasdaq believes that the rule should remain in effect on an uninterrupted basis.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 15A of the Act,[10] including section 15A(b)(6),[11] which requires, among other things, that a registered national securities association's rules be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, and, in general, protect investors and the public interest. Nasdaq believes the proposed rule change provides Nasdaq with clearer authority to respond to and alleviate market disruptions and thereby protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

In a letter dated July 27, 2001, Instinet Corporation (''Instinet'') commented on the proposed rule change as originally proposed and currently in effect.[12] Nasdaq has filed a proposed rule change to modify the rule in certain respects and to make the proposed rule change permanent.[13] Nasdaq believes that the amendments to the rule proposed in SR–NASD–2001–75 respond to the concerns expressed by Instinet without impairing the flexibility that the rule must retain in order for the rule to assist Nasdaq in meeting its overarching responsibility to maintain the fairness and orderly structure of the Nasdaq market. On October 2, 2002, the American Stock Exchange (''Amex'') submitted a letter comment on SR–NASD–2001–75.[14] On April 11, 2003, Nasdaq filed an amendment to SR–NASD–2001–75 that responds to the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] Nasdaq asked the Commission to waive the five-day pre-filing notice requirement and the 30-day operative delay. *See* rule 19b–4(f)(6)(iii). 17 CFR 240.19b–4(f)(6)(iii).

[6] *See* Securities Exchange Act Release No. 44307 (May 15, 2001), 66 FR 28209 (May 22, 2001)(SR–NASD–2001–37).

[7] *See* July 27, 2001, letter from Thomas P. Moran, Associate General Counsel, Nasdaq, to Alton Harvey, Division of Market Regulation (''Division''), Commission.

[8] *See* Securities Exchange Act Release No. 44609 (July 27, 2001), 66 FR 40761 (August 3, 2001)(SR–NASD–2001–37).

[9] *See* Securities Exchange Act Release Nos. 44870 (September 28, 2001), 66 FR 50701 (October 4, 2001)(SR–NASD–2001–60); 45344 (January 28, 2002), 67 FR 5022 (February 3, 2002)(SR–NASD–2002–14); 45851 (April 30, 2002), 67 FR 31858 (May 10, 2002)(SR–NASD–2002–57); 46559 (September 26, 2002), 67 FR 63003 (October 9, 2002)(SR–NASD–2002–125); and 46851 (November 19, 2002), 67 FR 70794 (November 26, 2002)(SR–NASD–2002–159).

[10] 15 U.S.C. 78o–3.

[11] 15 U.S.C. 78o–3(b)(6).

[12] *See* July 27, 2001, letter from Jon Kroeper, First Vice President, Regulatory Policy/Strategy, Instinet, to Jonathan G. Katz, Secretary, Commission.

[13] *See* Securities Exchange Act Release No. 45355 (January 29, 2002), 67 FR 5351 (February 5, 2002)(SR–NASD–2001–75).

[14] *See* October 2, 2002, letter from Richard T. Chase, Executive Vice President, Member Firm Regulation, Amex, to Jonathan G. Katz, Secretary, Commission.

Amex's comments.[15] Pending final Commission action on SR–NASD–2001–75, however, Nasdaq believes that the pilot period of the current rule should be extended to allow the rule to remain in effect on an uninterrupted basis.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) Impose any significant burden on competition; and

(iii) Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act[16] and rule 19b–4(f)(6) thereunder.[17] 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.

Nasdaq has asked the Commission to waive the five-day pre-filing notice requirement and the 30-day operative delay. The Commission believes waiving the five-day pre-filing notice requirement and the 30-day operative delay is consistent with the protection of investors and the public interest. Such waivers will allow the pilot to operate without interruption through August 15, 2003. For these reasons, the Commission designates the proposal to be effective and operative upon filing with the Commission.[18]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR–NASD–2003–82 and should be submitted by June 19, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[19]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–13448 Filed 5–28–03; 8:45 am]

BILLING CODE 8010–01–P

[15] *See* April 11, 2003 letter from John M. Yetter, Assistant General Counsel, Nasdaq, to Katherine A. England, Assistant Director, Division, Commission.

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6).

[18] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47912; File Nos. SR–NYSE–2002–49; SR–NASD–2002–154]

Self-Regulatory Organizations: Notice of Filing of Amendment No. 2 to Proposed Rule Changes by the New York Stock Exchange, Inc. Relating to Exchange Rules 344 (''Supervisory Analysts''), 345A (''Continuing Education for Registered Persons''), 351 (''Reporting Requirements'') and 472 (''Communications With the Public'') and by the National Association of Securities Dealers, Inc. Relating to NASD Rule 2711 (''Research Analysts and Research Reports'')

May 22, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 16, 2003, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') Amendment No. 2 to its proposed rule change (''NYSE Amendment No. 2''), which it originally filed on October 9, 2002 and subsequently amended on December 4, 2002.[3]

On May 20, 2003, the National Association of Securities Dealers, Inc. (''NASD'') filed Amendment No. 2 to its proposed rule change (''NASD Amendment No. 2''), which it originally filed on October 25, 2002 and subsequently amended on December 18, 2002.[4] The proposed rule changes, incorporating NYSE Amendment No. 1 and NASD Amendment No. 1, were published for comment in the **Federal Register** on January 7, 2003.[5]

NYSE Amendment No. 2 and NASD Amendment No. 2 are described in Items I, II, and III below, which Items have been prepared by the respective self-regulatory organizations (''SROs''). The Commission is publishing this notice to solicit comments on NYSE Amendment No. 2 and NASD Amendment No. 2 from interested persons.

I. Self-Regulatory Organizations' Statements of the Terms of Substance of the Proposed Rule Changes

The NYSE is filing with the SEC proposed amendments to NYSE Rule 472 (''Communications with the Public'') to conform to the requirements of the Sarbanes-Oxley Act of 2002 (''SOA''),[6] and providing for an interpretation to the public appearance and print media disclosure requirements of NYSE Rule 472.

NASD is submitting an amendment to SR–NASD–2002–154, a proposed rule change to strengthen rules that govern analyst conflicts of interest by amending NASD Rules 1120 and 2711 and creating a new NASD Rule 1050. NASD Amendment No. 2 would implement provisions of the SOA related to analyst conflicts of interest, create an exemption from some provisions of NASD Rule 2711 for certain smaller firms, and make certain other changes to the current rule.

Below is the text of the proposed rule changes. Proposed new language is in

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Darla Stuckey, Corporate Secretary, NYSE, to James A. Brigagliano, Assistant Director, Division of Market Regulation (''Division''), Commission (''NYSE Amendment No. 1''). NYSE Amendment No. 1 conformed aspects of the proposed NYSE rules to those of NASD (*See* SR–NASD–2002–154), and proposed effective dates for the various rule provisions.

[4] *See* Letter from Philip Shaikun, Assistant General Counsel, NASD, to Katherine A. England, Assistant Director, Division, Commission (''NASD Amendment No. 1''). NASD Amendment No. 1 clarified that only research analysts who are directly responsible for the preparation of research reports would be required to register with NASD and pass a qualification examination (*See* proposed NASD Rule 1050). NASD Amendment No. 1 also conformed NASD's proposed research analyst compensation provisions to comparable NYSE provisions. NASD Amendment No. 1 also amended the definition of ''research report'' to conform it to the definition in the Sarbanes-Oxley Act of 2002. NASD Amendment No. 1 also revised certain language that was contained in the discussion of the proposed amendment concerning print media interviews and articles.

[5] *See* Securities Exchange Act Release No. 47110 (December 31, 2002), 68 FR 826 (''Original Notice'').

[6] Pub. L. 107–204, 116 Stat. 745 (2002).

italics; proposed deletions are in [brackets].

A. *NYSE's Proposed Rule Text*

Rule 472 Communications With the Public

Approval of Communications and Research Reports

(a)(1) Each advertisement, market letter, sales literature or other similar type of communication which is generally distributed or made available by a member or member organization to customers or the public must be approved in advance by a member, allied member, supervisory analyst, or qualified person designated under the provisions of Rule 342(b)(1).

(2) Research reports must be [prepared or] approved, in advance, by a supervisory analyst acceptable to the Exchange under the provisions of Rule 344. Where a supervisory analyst does not have technical expertise in a particular product area, the basic analysis contained in such report may be co-approved by a product specialist designated by the organization. In the event that the member organization has no principal or employee qualified with the Exchange to approve such material, it must be approved by a qualified supervisory analyst in another member organization by arrangement between the two member organizations.

Investment Banking, Research Department and Subject Company Relationships and Communications

(b)(1) Research Department personnel or any associated person(s) engaged in the preparation of research reports may not be subject to the supervision or control of the Investment Banking Department of the member or member organization.

(2) Research reports may not be subject to review or approval prior to *publication* [distribution] by [the] Investment Banking [Department] *personnel or any other employee of the member or member organization who is not directly responsible for investment research ("non-research personnel") other than Legal or Compliance Department personnel.*

(*3*) [(2)] [Investment Banking personnel] *Non-research personnel* may *review* [check] research reports prior to *publication* [distribution] only to verify the factual accuracy of information *in the research report* [and] *or* to identify [or to review for] any potential conflicts of interest that may exist, provided that:

(i) any [such] written communication concerning the *content* [accuracy] of *a* research report[s] between [the Investment Banking] *non-research personnel* and Research [Departments] *personnel* must be made either through [the] Legal or Compliance [Department] *personnel* or in a transmission copied to Legal or Compliance *personnel;* and

(ii) any [such] oral communication concerning the *content* [accuracy] of *a* research report[s] between [the Investment Banking] *non-research personnel* and Research [Departments] *personnel* must be documented and made either with Legal or Compliance personnel acting as intermediary or in a conversation conducted in the presence of Legal or Compliance personnel.

(4) [(3)] A member or member organization may not submit a research report to the subject company prior to *publication,* [distribution,] except for the review of sections of a draft of the research report solely to verify facts. Members and member organizations may not, under any circumstances, provide the subject company sections of research reports that include the research summary, the research rating or the price target.

(i) Prior to submitting any sections of the research report to the subject company, the Research Department must provide a complete draft of the research report to the Legal or Compliance Department.

(ii) If after submission to the subject company, the Research Department intends to change the proposed rating or price target, the Research Department must provide written justification to, and receive prior written authorization from, the Legal or Compliance Department for any change. The Legal or Compliance Department must retain copies of any drafts and changes thereto of the research reports provided to the subject company.

(iii) The member or member organization may not notify a subject company that a rating will be changed until after the close of trading in the principal market of the subject company one business day prior to the announcement of the change.

(5) No member or member organization may publish or otherwise distribute a research report prepared by an associated person nor may an associated person make a public appearance concerning a subject company if the associated person engaged in any communication with the subject company in furtherance of obtaining investment banking business prior to the time the subject company entered into a letter of intent or other written agreement with the member or member organization designating the member or member organization as an underwriter of an initial public offering by the subject company. This provision shall not apply to any due diligence communication between the associated person and the subject company, the sole purpose of which was to analyze the financial condition and business operations of the subject company.

Written Procedures

(c) Each member and member organization must establish written procedures reasonably designed to ensure that members, member organizations, and their associated persons are in compliance with this Rule (see Rule 351(f) and *Rule 472(h)(2)* for attestations to the Exchange regarding compliance).

Retention of Communications

(d) Communications with the public prepared or issued by a member or member organization must be retained in accordance with Rule 440 ("Books and Records"). The names of the persons who prepared and who reviewed and approved the material must be ascertainable from the retained records and the records retained must be readily available to the Exchange, upon request.

Restrictions on Trading Securities by Associated Persons

(e)(1) No associated person or member of the associated person's household may purchase or receive an issuer's securities prior to its initial public offering (*e.g.,* so-called pre-IPO shares), if the issuer is principally engaged in the same types of business as companies (or in the same industry classification) which the associated person usually covers in research reports.

(2) No associated person or member of the associated person's household may trade in any recommended subject company's securities or derivatives of such securities for a period of thirty (30) calendar days prior to and five (5) calendar days after the member's or member organization's *publication* [issuance] of research reports concerning such security or a change in rating or price target of a subject company's securities.

(3) No associated person or member of the associated person's household may effect trades contrary to the member's or member organization's most current recommendations (*i.e.,* sell securities while maintaining a "buy" or "hold" recommendation, buy securities while maintaining a "sell" recommendation, or effecting a "short sale" in a security while maintaining a "buy" or "hold" recommendation on such security).

(4) The following are exceptions to the prohibitions contained in paragraphs (1), (2), and (3):

(i) transactions by associated persons and household members that have been pre-approved in writing by the Legal or Compliance Department that are made due to an unanticipated significant change in their personal financial circumstances;

(ii) a member or member organization may permit the *publication* [issuance] of research reports or permit a change to the rating or price target on a subject company, regardless of whether an associated person and/or household members traded the subject company's securities or derivatives of such securities, within the thirty (30) calendar day period described in paragraph (e)(2), when the *publication* [issuance] of such research reports, or change in such rating or price target is attributable to some significant news or events regarding the subject company, provided that the *publication* [issuance] of such research reports, or change in rating or price target on such subject company has been pre-approved in writing by the Legal or Compliance Department;

(iii) sale transactions by an associated person and/or household member who is new to the member or member organization within thirty (30) calendar days of such associated person's employment with the member or member organization when such associated person and/or household member had previously purchased such security or derivatives of such security prior to the associated person's employment with the member or member organization;

(iv) sale transactions by an associated person and/or household member within thirty (30) calendar days from the date of the member's or member organization's *publication* [issuance] of research reports or changes to the rating or price target on a subject company when such associated person and/or household member had previously purchased the subject company's securities or derivatives of such securities prior to initiation of coverage of the subject company by the associated person;

(v) transactions in accounts not controlled by the associated person and for investment funds in which an associated person or household member participates as a passive investor, provided the interest of the associated person or household member in the assets of the fund does not exceed 1% of the fund's assets, and the fund does not invest more than 20% of its assets in securities of issuers principally engaged in the same types of business as companies (or in the same industry classification) which the associated person usually covers in research reports. If an investment fund distributes securities in kind to an associated person before the issuer's initial public offering, the associated person must either divest those securities immediately or refrain from participating in the preparation of research reports concerning that issuer;

(vi) transactions in a registered diversified investment company as defined under section 5(b)(1) of the Investment Company Act of 1940.

Restrictions on Member's or Member Organization's Issuance of Research Reports *and Participation in Public Appearances*

(f)(1) A member or member organization may not *publish or otherwise distribute* [issue] research reports regarding an issuer *or recommend an issuer's securities in a public appearance,* for which the member or member organization acted as manager or co-manager of an initial public offering within forty (40) calendar days following the *offering date* [effective date of the offering].

(2) A member or member organization may not *publish or otherwise distribute* [issue] research reports regarding an issuer *or recommend an issuer's securities in a public appearance,* for which the member or member organization acted as manager or co-manager of a secondary offering within ten (10) calendar days following the *offering date* [effective date of the offering]. This prohibition shall not apply to research reports [issued] *published or otherwise distributed* under Securities Act Rule 139 regarding issuers whose securities are actively traded, as defined in Securities Exchange Act Rule 101(c)(1) of Regulation M.

(3) No member or member organization that has agreed to participate or is participating as an underwriter or dealer (other than as manager or co-manager) of an issuer's initial public offering may publish or otherwise distribute a research report regarding that issuer for twenty-five (25) calendar days following the offering date.

(4) No member or member organization which has acted as a manager or co-manager of a securities offering may publish or otherwise distribute a research report or make a public appearance within fifteen (15) days prior to or after the expiration, waiver or termination of a lock-up agreement or any other agreement that the member or member organization has entered into with a subject company and its shareholders that restricts or prohibits the sale of the subject company's or its shareholder's securities after the completion of a securities offering.

(5) [(3)] A member or member organization may permit exceptions to the prohibitions in paragraphs (f)(1), [and] (2), *(3) and (4)* (consistent with other securities laws and rules) for research reports that are *published or otherwise distributed* [issued] due to significant news or events, provided that such research reports are pre-approved in writing by the *member's or member's organization's* Legal or Compliance Department.

(6) If a member or member organization withdraws its research coverage of a subject company, notice of this withdrawal must be made. Such notice must be made in the same manner as when research coverage was first initiated by the member or member organization and must include the member's or member organization's final recommendation or rating.

Prohibition *on* [of] Offering Favorable Research for Business *and Retaliation Against Associated Persons*

(g)(*1*) No member or member organization may directly or indirectly offer a favorable research rating or specific price target, or offer to change a rating or price target, to a subject company as consideration or inducement for the receipt of business or for compensation.

(2) No member or member organization and no employee of a member or member organization who is involved with the member's or member organization's investment banking activities may, directly or indirectly, retaliate against or threaten to retaliate against any associated person employed by the member or member organization or its affiliates as a result of an adverse, negative, or otherwise unfavorable research report written or public appearance made by the associated person that may adversely affect the member's or member organization's present or prospective investment banking relationship with the subject company of a research report. This prohibition shall not limit a member's or member organization's authority to discipline or terminate an associated person, in accordance with the member's or member organization's policies and procedures, for any cause other than the writing of such an unfavorable research report or the making of such unfavorable public appearance.

Restrictions on Compensation to Associated Persons

(h)(*1*) No member or member organization may compensate an associated person(s) for specific investment banking services transactions. An associated person may not receive an incentive or bonus that is based on a specific investment banking services transaction. However, a member or member organization is not prohibited from compensating an associated person based upon such *member's or member organization's* [person's] overall performance, including [services provided to] the *performance of the* Investment Banking Department (see Rule 472(k)(2) for disclosure of such compensation).

(2) An associated person's compensation must be reviewed and approved at least annually by a committee which reports to the Board of Directors or, where the member or member organization has no Board of Directors, to a senior executive officer of the member or member organization. Such committee may not include representatives from the member's or member organization's Investment Banking Department. The committee must, among other things, consider the following factors, if applicable, when reviewing an associated person's compensation:

i. The associated person's individual performance, (e.g., productivity, and quality of research product);

ii. The correlation between the associated person's recommendations and stock price performance;

iii. The overall ratings received from clients, sales force, and peers independent of the Investment Banking Department, and other independent rating services.

The committee may not consider as a factor in determining the associated person's compensation, his or her contributions to the member's or member organization's investment banking business.

The committee must document the basis upon which each associated person's compensation was established. The annual attestation required by Rule 351(f) must certify that the committee reviewed and approved each associated person's compensation and has documented the basis upon which such compensation was established.

General Standards for All Communications

(Formerly positioned at Supplementary Material .30)

A. (i) No change.

Specific Standards for Communications

(Formerly positioned at Supplementary Material .40)

B. (j) No change (except for deletion of .40(2)).

Disclosure

(k)(1) Disclosures Required in Research Reports and Public Appearances Disclosure of Member's, Member Organization's, and Associated Person's Ownership of Securities *and Subject Company Relationships*

(i) A member or member organization must disclose in research reports and an associated person must disclose in public appearances:

a. if, as of the last day of the month before the publication or appearance (or the end of the second most recent month if the publication or appearance is less than ten (10) calendar days after the end of the most recent month), the member or member organization or its affiliates beneficially own 1% or more of any class of common equity securities of the subject company. The member or member organization must make the required beneficial ownership computation no later than ten (10) calendar days after the end of the prior month. Computation of beneficial ownership of securities must be based upon the same standards used to compute ownership for purposes of the reporting requirements under section 13(d) of the Securities Exchange Act of 1934,

b. if the associated person or a household member has a financial interest in the securities of the subject company, *and the nature of the financial interest, including, without limitation, whether it consists of any option, right, warrant, futures contract, long or short position,* [or]

c. *if the subject company currently is a client of the member or member organization or was a client of the member or member organization during the 12-month period preceding the date of distribution of the research report or date of the public appearance by the associated person (if the associated person knows or has reason to know). In such instances, the member or member organization or associated person (if such associated person knows or has reason to know) also must disclose the types of services provided to the subject company (For purposes of this paragraph, the types of services provided to the subject company may be described as investment banking services, non-investment banking-securities related services, and non-securities services.),*

d. [c.] any other actual, material conflict of interest of the *associated person,* or member *or* member organization, *of* which the associated person knows, or has reason to know, at the time the research report is *published* [issued] or at the time the public appearance is made.

e. if the associated person or member of the associated person's household is an officer, director, or advisory board member of the subject company; or

f. if the associated person received any compensation from the subject company in the past twelve (12) months.

Associated Person Disclosure

(ii) An associated person must disclose in public appearances (if the associated person knows or has reason to know) if the member or member organization or any affiliate thereof, received any compensation from the subject company in the past twelve (12) months.

Member, *Member* Organization*, and Affiliate* Compensation

(iii) [(ii)] A member or member organization must disclose in research reports if the member or member organization or its affiliates: (a) Has managed or co-managed a public offering of [equity] securities for the subject company in the past twelve (12) months; (b) has received compensation for investment banking services from the subject company in the past twelve (12) months; *(c) received any compensation other than for investment banking services from the subject company in the past twelve (12) months;* or *(d)* [c] expects to receive or intends to seek compensation for investment banking services from the subject company in the next three (3) months.

[When an associated person recommends securities in a public appearance, the associated person must disclose if the subject company is an investment banking services client of the member, member organization, or one of its affiliates; when the associated person knows or has reason to know of this relationship.]

[Disclosure of Associated Person's Affiliations With Subject Company

(iii) A member or member organization must disclose in research reports, and an associated person must disclose in public appearances, whether the associated person or member of the associated person's household is an officer, director or advisory board member of the recommended issuer.]

Exceptions to the Required Disclosures

(iv) A member or member organization or an associated person will not be required to make a

disclosure required by Rule 472(k)(1)(i)c. and (iii) (b) and (d) to the extent such disclosure would reveal material non-public information regarding specific potential future investment banking services transactions of the subject company.

(k)(2) Disclosures Specific to Research Reports.

The front page of a research report either must include the disclosures required under this Rule or must refer the reader to the page(s) on which each such disclosure is found. Disclosures, and references to disclosures, must be clear, comprehensive, and prominent.

A member or member organization must disclose in research reports if the associated person preparing such reports received compensation that is based upon (among other factors) the member's or member organization's overall investment banking revenues.

A member or member organization must disclose in research reports that recommend securities:

(i) if it is making a market in the subject company's securities at the time the research report is issued.

(ii) the valuation methods used, and any price objectives must have a reasonable basis and include a discussion of risks.

(iii) the meanings of all ratings used by the member or member organization in its ratings system. (For example, a member or member organization might disclose that a ''strong buy'' rating means that the rated security's price is expected to appreciate at least 10% faster than other securities in its sector over the next *twelve* (12)-month period[)]. Definitions of ratings terms also must be consistent with their plain meaning. Therefore, for example, a ''hold'' rating should not mean or imply that an investor should sell a security.)

(iv) the percentage of all securities that the member or member organization recommends an investor ''buy,'' ''hold,'' or ''sell.'' Within each of the three (*3*) categories, a member or member organization must also disclose the percentage of subject companies that are investment banking services clients of the member or member organization within the previous twelve (12) months[.] ([S]see Rule 472.70 for further information[.]).

(v) a chart that depicts the price of the subject company's stock over time and indicates points at which a member or member organization assigned or changed a rating or price target. This provision would apply only to securities that have been assigned a rating for at least one *(1)* year, and need not extend more than three *(3)* years prior to the date of the research report. The information in the price chart must be current as of the end of the most recent calendar quarter (or the second most recent calendar quarter if the publication date is less than fifteen (15) calendar days after the most recent calendar quarter).

When a member or member organization distributes a research report covering six (6) or more subject companies for purposes of the disclosures required in paragraph (k) of this Rule, such research report may direct the reader in a clear and prominent manner as to where they may obtain applicable current disclosures in written or electronic format.

Other Communications Activities

(l) Other communications activities are deemed to include, but are not limited to, conducting interviews with the media, writing books, conducting seminars or lecture courses, writing newspaper or magazine articles, or making radio/TV appearances.

Members and member organizations must establish specific written supervisory procedures applicable to members, allied members, and employees who engage in these types of communications activities. These procedures must include provisions that require prior approval of such activity by a person designated under the provisions of Rule 342(b)(1). These types of activities are subject to the general standards set forth in paragraph (i). In addition, any activity which includes discussion of specific securities and/or industries is subject to the specific standards in paragraph (j) and the disclosure requirements of paragraphs (k)(1) and (k)(2)(i).

Small Firm Exception

(m) The provisions of Rule 472(b)(1), (2) and (3) do not apply to members and member organizations that over the three previous years, on average per year, have participated in 10 or fewer investment banking services transactions as manager or co-manager and generated $5 million or less in gross investment banking services revenues from those transactions. For purposes of this paragraph the term ''investment banking services transactions'' shall include both debt and equity underwritings. Members and member organizations that qualify for this exemption must maintain records for three years of any communications that, but for this exemption, would be subject to paragraphs (b)(1), (2), and (3) of this Rule.

.10 Definitions

(1) Communication—The term ''Communication'' is deemed to include, but is not limited to, advertisements, market letters, research reports, sales literature, electronic communications, communications in and with the press, and wires and memoranda to branch offices or correspondent firms which are shown or distributed to customers or the public.

(2) Research Report—''Research report'' is generally defined as a written or electronic communication which includes an analysis of equity securities of individual companies or industries, *and* provides information reasonably sufficient upon which to base an investment decision [and includes a recommendation].

For purposes of approval by a supervisory analyst pursuant to Rule 472(a)(2), research report includes, but is not limited to, reports which recommend equity securities, derivatives of such securities, including options, debt and other types of fixed income securities, single stock futures products, and other investment vehicles subject to market risk.

(3) Advertisement—''Advertisement'' is defined to include, but is not limited to, any sales communications that is published, or designed for use in any print, electronic or other public media such as newspapers, periodicals, magazines, radio, television, telephone recording, Web sites, motion pictures, audio or video device, telecommunications device, billboards, or signs.

(4) Market letters—''Market letters'' are defined as, but are not limited to, any written comments on market conditions, individual securities, or other investment vehicles that are not defined as research reports. They also may include ''follow-ups'' to research reports and articles prepared by members or member organizations which appear in newspapers and periodicals.

(5) Sales literature—''Sales literature'' is defined as, but is not limited to, written or electronic communications including, but not limited to, telemarketing scripts, performance reports or summaries, form letters, seminar texts, and press releases discussing or promoting the products, services, and facilities offered by a member or member organization, the role of investment in an individual's overall financial plan, or other material calling attention to any other communication.

.20 For purposes of this Rule, ''investment banking services'' includes, without limitation, acting as an underwriter in an offering for the issuer; acting as a financial adviser in a merger or acquisition; providing venture

capital, equity lines of credit, PIPEs (private investment, public equity transaction), or similar investments; or serving as placement agent for the issuer.

.30 For purposes of this Rule, the term ''Investment Banking Department'' means any department or division of the member or member organization, whether or not identified as such, that performs any investment banking services on behalf of the member or member organization.

.40 For purposes of this Rule, the term ''associated person'' includes a member, allied member, or employee of a member or member organization responsible for, and any person who reports directly or indirectly to such associated person in connection with, the *preparation* of [making of the recommendation to purchase, sell or hold an equity security in] research reports, or *making recommendations or offering opinions in* public appearances or establishing a rating or price target of a subject company's equity securities. For purposes of this Rule, the term ''household member'' means any individual whose principal residence is the same as the associated person's principal residence. Paragraphs (e)(1), (2), (3); (4)(i), (ii), (iii), (iv) and (v); (k)(1)(i)b., *and (k)(1)(i)e.* [(k)(1)(iii)] apply to any account in which an associated person has a financial interest, or over which the associated person exercises discretion or control, other than an investment company registered under the Investment Company Act of 1940.

This term ''associated person'' also includes such ''other persons,'' e.g., Director of Research, Supervisory Analyst, or member of a committee, who have direct influence and/or control with respect to (1) preparing research reports, or (2) establishing or changing a rating or price target of a subject company's equity securities. Such other persons are subject to the provisions of paragraph (e)(1)–(4) of this Rule.

.50 For purposes of this Rule, the term ''public appearance'' includes, without limitation, participation in a seminar, forum (including an interactive electronic forum), radio, [or] television *or print* media interview, or other public appearance or public speaking activity, *or the writing of a newspaper article or other type of public written medium* in which an associated person makes a recommendation or offers an opinion concerning [an] *any* equity [security] *securities and/or industries.*

.60 For purposes of this Rule, ''subject company'' is the company whose equity securities are the subject of research reports.

.70 For purposes of Rule 472(k)(2)(iv), a member or member organization must determine, based on its own ratings system, into which of the three (3) categories each of their securities ratings utilized falls. This information must be current as of the end of the most recent calendar quarter (or the second most recent calendar quarter if the publication date is less than fifteen (15) calendar days after the most recent calendar quarter). For example, a research report might disclose that the member or member organization has assigned a ''buy'' rating to 58% of the securities that it follows, a ''hold'' rating to 15%, and a ''sell'' rating to 27%.

Rule 472(k)(2)(iv) requires members or member organizations to disclose the percentage of companies that are investment banking services clients for each of the three ratings categories within the previous twelve (12) months. For example, if *twenty* (20) of the *twenty-five* (25) companies to which a member or member organization has assigned a ''buy'' rating are investment banking clients of the member or member organization, the member or member organization would have to disclose that 80% of the companies that received a ''buy'' rating are its investment banking clients. Such disclosure must be made for the ''buy,'' ''hold'' and ''sell'' ratings categories as appropriate.

.80 For purposes of this Rule, the term ''Legal or Compliance Department'' also includes, but is not limited to, any department of the member or member organization which performs a similar function.

.90 For purposes of Rule 472(a)*(1),* a qualified person is one who has passed an examination acceptable to the Exchange.

.100 For purposes of this Rule, the term ''initial public offering'' refers to the initial registered equity security offering by an issuer, regardless of whether such issuer is subject to the reporting requirements of section 13 or 15(d) of the Securities Exchange Act of 1934, prior to the time of the filing of such issuer's registration statement.

.110 For purposes of this Rule, a secondary offering shall include a registered follow-on offering by an issuer or a registered offering by persons other than the issuer involving the distribution of securities subject to Regulation M of the Securities Exchange Act of 1934.

.120 *For purposes of this Rule, the term ''offering date'' refers to the later of the effective date of the registration statement or the first date on which the security was bona fide offered to the public.*

Reporting Requirements

Rule 351

(a)–(e) No change.

(f) Each member and member organization that prepares, issues or distributes [communications to the public, (including but not limited to,] research reports *and whose associated persons make public appearances* [, media presentations and interviews)], is required to submit to the Exchange annually, a letter of attestation signed by a senior officer or partner that the member or member organization has established and implemented procedures reasonably designed to comply with the provisions of Rule 472. *The attestation must also specifically certify that each associated person's compensation was reviewed and approved in accordance with the requirements of Rule 472(h)(2) and that the basis for such approval has been documented.*

* * * * *

.11 For purposes of Rule 351(f), the attestation must be submitted by April 1 of each year.

.12 The term ''research report'' is defined in Rule 472.10 and the term ''public appearance'' is defined in Rule 472.50.

Securities Analysts and Supervisory Analysts

Rule 344. *Securities analysts and supervisory analysts must be registered with, qualified by, and approved by the Exchange.*

[Supervisory analysts required under Rule 472 shall be acceptable to, and approved by, the Exchange.]

.10 For purposes of this Rule, the term ''securities analyst'' includes a member, allied member, or employee who is directly responsible for the preparation of research reports. Securities analyst candidates must pass a qualification examination acceptable to the Exchange.

.11 [.10] *For purposes of this Rule, the term ''supervisory analyst'' includes a member, allied member, or employee who is responsible for approving research reports under Rule 472(a)(2).* In order to show evidence of acceptability to the Exchange as a supervisory analyst, a member, allied member, or employee may do one of the following:

(1) Present evidence of appropriate experience and pass an Exchange Supervisory Analyst[s] Examination (*Series 16*).

(2) Present evidence of appropriate experience and successful completion of

a specified level of the Chartered Financial Analysts Examination prescribed by the Exchange and pass only that portion of the Exchange Supervisory Analyst[s] Examination (*Series 16*) dealing with Exchange rules on research standards and related matters.

[In addition, if not a member, allied member or registered representative, the candidate is subject to Exchange investigation of character and conduct and should submit personal information on Form U–4 for this purpose.]

The Exchange publishes a Study Outline for the *Securities Analyst Examination and the* Supervisory Analyst[s] Examination (*Series 16*). [Examinations are requested and given under the procedures described in Para. of 2345.15 for registered representative examinations.]

Continuing Education for Registered Persons

Rule 345A. (a) Regulatory Element—No change.

(b) Firm Element.

(1) Persons Subject to the Firm Element—The requirements of section (b) of this Rule shall apply to any registered person who has direct contact with customers in the conduct of the member's or member organization's securities sales, trading or investment banking activities, and to the immediate supervisors of such persons, *and to registered persons who function as* supervisory analysts, *and securities analysts as defined in Rule 344* (collectively, ''covered registered persons'').

(2) Standards—No Change.

(3) Participation in the Firm Element—No Change.

(4) Specific Training Requirements—The Exchange may require a member or member organization, either individually or as part of a larger group, to provide specific training to its covered registered persons in such areas the Exchange deems appropriate. Such a requirement may stipulate the class of covered registered persons for which it is applicable, the time period in which the requirement must be satisfied and, where appropriate, the actual training content.

.10 For purposes of this Rule, the term ''registered person'' means any member, allied member, registered representative, or other person registered or required to be registered under Exchange rules, but does not include any such person whose activities are limited solely to the transaction of business on the Floor with members or registered broker-dealers. *For purposes of the Regulatory Element required under Rule 345A(a), the term does not include persons registered as securities analysts, or supervisory analysts pursuant to Rule 344.*

.20–.40 No Change.

.50 Pursuant to Rule 345A(b)(1), all persons registered as securities analysts and supervisory analysts pursuant to Rule 344 must participate in a Firm Element Continuing Education program that includes training in applicable rules and regulations, ethics, and professional responsibility.

Interpretation

Rule 472 Communications With the Public

(k)(1) Disclosure Required in Research Reports and Public Appearances.

/01 Public Appearances—Print Media.

When an associated person recommends securities in a print or broadcast media interview, newspaper article or other type of public medium all of the disclosures required under Rule 472(k)(1) are required to be provided to the media outlet for inclusion in the published interview, article, broadcast, or other medium.

Whenever an associated person recommends securities in a print media interview, newspaper article prepared under his or her name, or broadcast, the associated person, before the opening of business on the next business day, must prepare a record of such interview, article or broadcast. Such record must include, at minimum, the name of the analyst(s), the name of the publication, the date of the interview, article, or broadcast the name of the interviewer (if applicable), the name(s) of the securities recommended and the specific disclosures provided to the print or broadcast media source and/or interviewer. Such record must be made regardless of whether the media outlet published or broadcast the required disclosures. The associated person's member or member organization must retain the record of such interview, article, or broadcast and the disclosures made in accordance with Rules 17a–and 17a–4 of the Securities Exchange Act of 1934. The record retained must be readily available to the Exchange, upon request.

B. *NASD's Proposed Rule Text*

1050. Registration of Research Analysts

All persons associated with a member who are to function as research analysts as that term is defined in Rule 2711 shall be registered with NASD. Before their registrations can become effective, they shall pass a Qualification Examination for Research Analysts as specified by the Board of Governors. For purposes of this Rule 1050, ''research analyst'' shall mean an associated person who is directly responsible for the preparation of research reports.

* * * * *

1120. Continuing Education Requirements

This Rule prescribes requirements regarding the continuing education of certain registered persons subsequent to their initial qualification and registration with the Association. The requirements shall consist of a Regulatory Element and a Firm Element as set forth below.

(a) Regulatory Element

(1) through (4) No change.

(5) Definition of Registered Person.

For purposes of this Rule, the term ''registered person'' means any person registered with [the Association] *NASD* as a representative, principal, [or] assistant representative *or research analyst* pursuant to Rule 1020, 1030, 1040, *1050* and 1110 Series.

(6) No change.

(b) Firm Element

(1) Persons Subject to the Firm Element.

The requirements of this subparagraph shall apply to any person registered with the member who has direct contact with customers in the conduct of the member's securities sales, trading and investment banking activities, and to the immediate supervisors of such persons, *and to any person registered as a research analyst pursuant to Rule 1050* (collectively, ''covered registered persons''). ''Customer'' shall mean any natural person and any organization, other than another broker or dealer, executing securities transactions with or through or receiving investment banking services from a member.

(2) Standards for the Firm Element.

(A) No change.

(B) Minimum Standards for Training Programs—Programs used to implement a member's training plan must be appropriate for the business of the member and, at a minimum must cover the following matters concerning securities products, services, and strategies offered by the member:

(i) General investment features and associated risk factors;

(ii) Suitability and sales practice considerations; [and]

(iii) Applicable regulatory requirements[.]*; and*

(iv) With respect to registered research analysts, training in ethics, professional responsibility and the requirements of Rule 2711.

(3) through (4) No change.

* * * * *

2711. Research Analysts and Research Reports

(a) Definitions

For purposes of this rule, the following terms shall be defined as provided.

(1) through (3) No change.

(4) ''Public appearance'' means any participation in a seminar, forum (including an interactive electronic forum), radio, television *or print media* interview, or other public speaking activity, *or the writing of a print media article,* in which a research analyst makes a recommendation or offers an opinion concerning an equity security.

(5) ''Research analyst'' means the associated person who is principally responsible for, and any associated person who reports directly or indirectly to such a research analyst in connection with, preparation of the substance of a research report, whether or not any such person has the job title of ''research analyst.'' *Solely for purposes of paragraph (g), the term ''research analyst'' also includes such other persons as the director or research, supervisory analyst, or member of a committee who have direct influence or control with respect to (A) the preparation of research reports, or (B) establishing or changing a rating or price target of a subject company's equity securities.*

(6) through (7) No change.

(8) ''Research report'' means a written or electronic communication which includes an analysis of equity securities of individual companies or industries, and which provides information reasonably sufficient upon which to base an investment decision [and includes a recommendation].

(9) No change.

(b) Restrictions on [Investment Banking Department] Relationships with Research Department

(1) No research analyst may be subject to the supervision or control of any employee of the member's investment banking department.

(2) Except as provided in paragraph (b)(3), no employee of the investment banking department *or any other employee of the member who is not directly responsible for investment research (''non-research personnel''), other than legal or compliance personnel,* may review or approve a research report of the member before its publication.

(3) [Investment banking] *Non-research* personnel may review a research report before its publication as necessary only to verify the factual accuracy of information in the research report or [to review the research report for] *identify* any potential conflict of interest, provided that:

(A) any written communication between [investment banking] *non-research personnel* and research department personnel concerning [such] *the content* of a research report must be made either through [an] authorized legal or compliance [official] *personnel* of the member or in a transmission copied to such [an official] *personnel;* and

(B) any oral communication between [investment banking] *non-research personnel* and research department personnel concerning [such] *the content of* a research report must be documented and made either through [an] authorized legal or compliance [official] *personnel* acting as intermediary or in a conversation conducted in the presence of such [an official] *personnel.*

(c) Restrictions on Review of a Research Report by the Subject Company

(1) No change.

(2) A member may submit sections of such a research report to the subject company before its publication for review as necessary only to verify the factual accuracy of information in those sections, provided that:

(A) No change.

(B) a complete draft of the research report is provided to [the] legal or compliance [department] *personnel* before sections of the report are submitted to the subject company; and

(C) if after submitting the sections of the research report to the subject company the research department intends to change the proposed rating or price target, it must first provide written justification to, and receive written authorization from, [the] legal or compliance [department] *personnel* for the change. The member must retain copies of any draft and the final version of such a research report for three years following its publication.

(3) No change.

(4) No research analyst may issue a research report or make a public appearance concerning a subject company if the research analyst engaged in any communication with the subject company in furtherance of obtaining investment banking business prior to the time the subject company entered into a letter of intent or other written agreement with the member designating the member as an underwriter of an initial public offering by the subject company. This provision shall not apply to any due diligence communication between the research analyst and the subject company, the sole purpose of which was to analyze the financial condition and business operations of the subject company.

(d) [Prohibition of Certain Forms of] *Restrictions on* Research Analyst Compensation

(1) No member may pay any bonus, salary or other form of compensation to a research analyst that is based upon a specific investment banking services transaction.

(2) A research analyst's compensation must be reviewed and approved at least annually by a committee that reports to the member's board of directors, or when the member has no board of directors, to a senior executive officer of the member. This committee may not have representation from the member's investment banking department. The committee must consider the following factors when reviewing a research analyst's compensation, if applicable:

(A) the research analyst's individual performance, including the analyst's productivity and the quality of the analyst's research;

(B) the correlation between the research analyst's recommendations and the stock price performance; and

(C) the overall ratings received from clients, sales force, and peers independent of the member's investment banking department, and other independent ratings services.

The committee may not consider as a factor in determining the research analyst's compensation his or her contributions to the member's investment banking business. The committee must document the basis upon which each research analyst's compensation was established. The annual attestation required by Rule 2711(i) must certify that the committee reviewed and approved each research analyst's compensation and documented the basis upon which this compensation was established.

(e) No change.

(f) [Imposition of Quiet Periods] *Restrictions on Publishing Research Reports and Public Appearances; Termination of Coverage*

(1) No member may publish *or otherwise distribute* a research report regarding a subject company *or recommend a subject company's securities in a public appearance* for

which the member acted as manager or co-manager of:

[(1)]*(A)* an initial public offering, for 40 calendar days following the date of the offering; or

[(2)]*(B)* a secondary offering, for 10 calendar days following the date of the offering; provided that:

[(A)]*(i)* paragraphs (f)(1)*(A)* and (f)[(2)]*(1)(B)* will not prevent a member from publishing *or otherwise distributing* a research report concerning the effects of significant news or a significant event on the subject company within such 40- and 10-day periods, and provided further that [the] legal [and] *or* compliance [department] *personnel* authorize[s] publication of that research report before it is [issued] *published or otherwise distributed;* and

[(B)]*(ii)* paragraph (f)[(2)]*(1)(B)* will not prevent a member from publishing *or otherwise distributing* a research report pursuant to SEC Rule 139 regarding a subject company with ''actively-traded securities,'' as defined in Regulation M, 17 CFR 242.101(c)(1).

(2) No member that has agreed to participate or is participating as an underwriter or dealer (other than as manager or co-manager) of an issuer's initial public offering may publish or otherwise distribute a research report regarding that issuer for 25 calendar days following the date of the offering.

(3) For purposes of paragraphs (f)(1) and (f)(2), the term ''date of the offering'' refers to the later of the effective date of the registration statement or the first date on which the security was bona fide offered to the public.

(4) No member that has acted as a manager or co-manager of a securities offering may publish or otherwise distribute a research report or make a public appearance concerning a subject company 15 days prior to and after the expiration, waiver or termination of a lock-up agreement or any other agreement that the member has entered into with a subject company or its shareholders that restricts or prohibits the sale of securities held by the subject company or its shareholders after the completion of a securities offering. This paragraph will not prevent a member from publishing or otherwise distributing a research report concerning the effects of significant news or a significant event on the subject company within such period, provided that legal or compliance personnel authorize publication of that research report before it is issued.

(5) If a member intends to discontinue its research coverage of a subject company, notice of this withdrawal must be made in the same manner as when research coverage was first initiated by the member and must include the member's final recommendation or rating.

(g) Restrictions on Personal Trading by Research Analysts

(1) No change.

(2) (A) No change.

(B) a member may permit a research analyst account to purchase or sell any security issued by a subject company within 30 calendar days before the publication of a research report or change in the rating or price target of the subject company's securities due to significant news or a significant event concerning the subject company, provided that [the member's] legal or compliance [department] *personnel* pre-approve[s] the research report and any change in the rating or price target.

(3) No change.

(4) [A member's l]*Legal* or compliance [department] *personnel* may authorize a transaction otherwise prohibited by paragraphs (g)(2) and (g)(3) based upon an unanticipated significant change in the personal financial circumstances of the beneficial owner of the research analyst account, provided that:

(A) [the] legal or compliance [department] *personnel* authorize[s] the transaction before it is entered;

(B) through (C) No change.

(5) No change.

(h) Disclosure Requirements

(1) No change.

(2) Receipt of Compensation.

(A) A member must disclose in research reports if [:(i)] the research analyst principally responsible for preparation of the report received compensation that is based upon (among other factors) the member's investment banking revenues.[; and]

(B)[(ii) the member or its affiliates:] *A member must disclose in research reports if the member or any affiliate:*

(i)[(a)]managed or co-managed a public offering of securities for the subject company in the past 12 months;

(ii)[(b)] received compensation for investment banking services from the subject company in the past 12 months; or

(iii)[(c)] expects to receive or intends to seek compensation for investment banking services from the subject company in the next 3 months.

(C) A member must disclose in research reports if the member or any affiliate received any compensation other than for investment banking services from the subject company in the past 12 months.

(D) A member must disclose in research reports and a research analyst must disclose in public appearances if the research analyst received any compensation from the subject company in the past 12 months.

(E) A research analyst must disclose in public appearances (if the analyst knows or has reason to know) if the member or any affiliate received any compensation from the subject company in the past 12 months.

(F) A member must disclose in research reports and a research analyst must disclose in public appearances (if the analyst knows or has reason to know) if the subject company currently is a client of the member or was a client of the member during the 12-month period preceding the date of distribution of the research report or date of the public appearance. In such cases, the member or research analyst (if the analyst knows or has reason to know) also must disclose the types of services provided to the subject company. For purposes of this paragraph (h)(2)(F), the types of services provided to the subject company may be described as investment banking services, non-investment banking securities-related services, and non-securities services.

(G) A member or research analyst will not be required to make a disclosure required by paragraphs (h)(2)(B)(ii), (h)(2)(B)(iii), or (h)(2)(F) to the extent such disclosure would reveal material non-public information regarding specific potential future investment banking services transactions of the subject company.

[(B) A research analyst must disclose in public appearances if the analyst knows or has reason to know that the subject company is a client of the member or its affiliates.]

(3) through (11) No change.

(i) No change.

(j) Prohibition of Retaliation Against Research Analysts

No member and no employee of a member who is involved with the member's investment banking activities may, directly or indirectly, retaliate against or threaten to retaliate against any research analyst employed by the member or its affiliates as a result of an adverse, negative, or otherwise unfavorable research report or public appearance written or made by the research analyst that may adversely affect the member's present or prospective investment banking relationship with the subject company of a research report. This prohibition shall not limit a member's authority to discipline or terminate a research analyst, in accordance with the member's policies and procedures, for any cause other than the writing of such

an unfavorable research report or the making of such an unfavorable public appearance.

(k) Exemption for Small Firms

The provisions of paragraph (b) shall not apply to members that over the previous three years, on average per year, have participated in 10 or fewer investment banking services transactions as manager or co-manager and generated $5 million or less in gross investment banking services revenues from those transactions. For purposes of this paragraph (k), the term ''investment banking services transactions'' includes the underwriting of both debt and equity securities. Members that qualify for this exemption must maintain records for three years of any communication that, but for this exemption, would be subject to paragraph (b) of this Rule.

II. Self-Regulatory Organizations' Statements of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

In their filings with the Commission, the NYSE and NASD included statements concerning the purpose of, and statutory basis for, the proposed rule changes. The text of these statements may be examined at the places specified in Item IV below. The NYSE and NASD have prepared summaries, set forth in sections A, B, and C below of the most significant aspects of such statements.

A. Self-Regulatory Organizations' Statements of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

1. NYSE's Purpose

The Exchange recently adopted sweeping and dramatic rule changes governing the manner in which members and member organizations, their investment banking departments and associated persons (hereinafter referred to as research analysts) manage and disclose conflicts of interest between their investment-banking and research departments. According to NYSE, these amendments were precipitated by a series of events that had eroded investor confidence in the equities markets and called into question the ways in which these conflicts of interest were managed and disclosed to the investing public. According to the NYSE, the additional amendments, pending approval of the SEC and new proposed changes discussed below, were developed by the Exchange in collaboration with the NASD under the guidance of the SEC.

The Exchange believes that the amendments to the NYSE rules proposed in this filing are necessary in order to comply with the mandates of the SOA, which amends the Exchange Act [7] by adding new section 15D [8] which requires the SEC, ''or upon authorization and direction of the Commission, a self-regulatory organization,'' to adopt not later than one year after July 30, 2002, the date of enactment of the SOA, ''rules reasonably designed to address conflicts of interest that can arise when securities analysts recommend equity securities in research reports and public appearances, in order to improve the objectivity of research and provide investors with more useful and reliable information.'' [9]

The Exchange believes that certain of the disclosure requirements and prohibitions that the SOA mandates have already been adopted in new NYSE Rules. The Exchange believes that the SOA appears to impose different, and in some instances more stringent, requirements than current NYSE Rule 472. According to NYSE, given the complexity and possible ramifications of the changes necessitated by the SOA, the SROs in conjunction with the SEC, spent considerable time examining which aspects of the SRO rules would require further amendments. Accordingly, proposed conforming SOA changes are being made in two phases. In the Original Notice, the Exchange proposed an amendment, discussed below, to the definition of the term ''research report'' contained in NYSE Rule 472.10(2), to conform to the requirements of section 15D(c)(2) of the Exchange Act.[10] The Exchange also proposed an amendment, discussed below, that it believes would satisfy the requirements of section 15D(a)(1)(B) of the Exchange Act by limiting the ''compensatory evaluation of securities analysts to officials employed by the broker or dealer who are not engaged in investment banking activities.'' [11] These proposed amendments are pending with the Commission. According to NYSE, as discussed in more detail below, the Exchange is currently proposing further amendments to its rules in order to conform to the requirements of the SOA.

February 2002 Filing

In February 2002, the Exchange filed with the Commission proposed amendments to Exchange Rules 472 and 351, which were approved by the Commission in May 2002.[12] In the May 10th Order, the SEC also simultaneously approved comparable changes to NASD rules (new NASD Rule 2711—''Research Analysts and Research Reports'').

The rule amendments generally: restrict the relationship between research and investment banking departments and the companies that are the subjects of research reports; require disclosure of a financial interest in a subject company by an analyst or a member or member organization; require disclosure of existing and potential investment banking relationships with a subject company; impose quiet periods for the issuance of research reports following the completion of a company's securities offering; restrict personal trading by research analysts in the securities of the companies covered by such analysts; and generally require extensive disclosure in research reports of certain important information to help customers monitor the correlation between a research analyst's ratings and the price movements of subject companies' securities.

The rule amendments have been phased in incrementally to provide members and member organizations time to develop and implement policies, procedures and systems and hire additional personnel to comply with the new requirements. The staggered implementation of the SRO rules began July 9, 2002, with September 9, 2002 and November 6, 2002 as the effective dates for certain specified provisions.

According to NYSE, as a result of comments received, the SEC approved, on a temporary basis, NYSE rule proposals providing for an exemption from the gatekeeper provisions (NYSE Rules 472(b)(1), (2), and (3)) for members and member organizations that over the three previous years, on average per year, have participated in ten or fewer investment banking services transactions as manager or co-manager and generated $5 million or less in gross investment banking revenues from those transactions (hereinafter referred to as ''small firms'').[13] As discussed in more detail below, the NYSE is proposing that certain elements of the temporary small firm exemption to the gatekeeper provisions be made permanent. During

[7] 15 U.S.C. 78a *et seq.*

[8] 15 U.S.C. 78o–6.

[9] *Id.* at (a).

[10] 15 U.S.C. 78o–6 (c)(2).

[11] 15 U.S.C 78o–6(a)(1)(B).

[12] *See* Securities Exchange Act Release No. 45908 (May 10, 2002), 67 FR 34969 (May 16, 2002) (''May 10th Order'').

[13] *See* Securities Exchange Act Release No. 46182 (July 11, 2002), 67 FR 47013 (July 17, 2002); Securities Exchange Act Release No. 46949 (December 4, 2002), 67 FR 76202 (December 11, 2002).

the interim period, the Exchange, in a separate filing, extended the implementation date for the gatekeeper provisions for small firms until July 30, 2003, or until such date as a permanent exemption is approved by the SEC and becomes effective.[14]

According to NYSE, as a result of numerous interpretive requests, on June 26, 2002, the Exchange and the NASD issued interpretive guidance to certain rule provisions.[15] According to NYSE, upon adoption of the new amendments to the SRO rules, the SROs intend to provide written clarification as to how these rules will impact existing guidance in this area as well as additional issues that may arise once the amendments are adopted.

According to the NYSE, the Exchange, together with other regulatory organizations, also conducted examinations of members' and member organizations' research practices to determine compliance with the new SRO Rules. The Exchange believes that some of the interpretive issues raised by the industry and the preliminary findings from the examinations necessitated certain additional changes, discussed below, to existing NYSE Rules.

October 2002 Filing

In October 2002, the Exchange filed with the SEC proposed amendments to Exchange Rules 472, 351, 344 and 345A.[16] Comparable amendments were also filed by the NASD. The amendments pending with the SEC generally provide for further restrictions on research analysts' compensation, trading activities, issuance of research reports, and notification of research coverage termination, and impose additional disclosure requirements for research reports and research analysts. In addition, pending amendments place certain restrictions on research analysts participating in solicitation or ''pitch'' meetings with prospective investment banking clients.

Amendments pending with the SEC expand the definition of ''research analyst'' (associated person) to include research directors, supervisory analysts and others, (*e.g.*, committee members who have direct influence, or control over the preparation of research reports and establishment or change in ratings or price targets) and thereby subject them to the same trading and ownership prohibitions that the Rule imposes on research analysts.

Following approval, the current 10 and 40-day quiet periods for the issuance of research reports by managers and co-managers of initial and secondary offerings will be extended to include public appearances.

Upon approval by the SEC, the definition of ''public appearance'' will be amended to include research analysts' making a recommendation in a newspaper article or similar public medium. Extending the definition of ''public appearance'' to recommendations in a newspaper article will require research analysts to make the same disclosures that they are required to make in other public appearances. As discussed in more detail below, the Exchange received comments on this proposed amendment.

Proposed amendments to NYSE Rule 344 (''Supervisory Analysts'') pending with the SEC would establish a new registration category and require a qualification examination for research analysts (NYSE Rule 344). In addition, NYSE Rule 345A (''Continuing Education for Registered Persons'') would be amended to include research analysts and supervisory analysts as covered persons subject to the Firm Element of the Continuing Education Program to address applicable rules and regulations, ethics, and professional responsibility.

According to NYSE, pending proposed amendments to the definition of ''research report'' began the process of conforming NYSE Rules to the mandates of the SOA. As proposed, the term ''research report'' as it is currently defined in the NYSE Rule 472.10(2) is being amended to conform to the SOA's definition by deleting the criterion of providing a recommendation from the criteria that determines what constitutes a research report.

According to NYSE, the Exchange filed NYSE Amendment No. 1 for the purpose of conforming proposed NYSE rules to those of the NASD and to establish effective dates, noted below, for the various rule provisions.

Sarbanes-Oxley Act Compliance

According to NYSE, as a result of discussions with the NASD and SEC, the Exchange is filing Amendment No. 2 to propose the following additional changes to NYSE Rule 472 to conform it to the requirements of the SOA.

Section 15D(a)(1)(A) of the Exchange Act requires that rules be designed to restrict ''the prepublication review or approval of research reports by persons employed by the broker-dealer who are engaged in investment banking activities, or persons not directly responsible for investment research, other than legal or compliance staff.'' [17] In the May 10th Order, the Commission approved NYSE Rule 472(b)(1), which prohibits investment banking department review and approval of research reports prior to distribution. According to NYSE, the purpose of that amendment was to help promote fair, objective and unbiased research through the elimination of potential conflicts of interest that are present when an investment banker is able to review, and possibly influence, a research report prior to its publication.

In accordance with the requirements of section 15D(a)(1)(A) of the Exchange Act,[18] the Exchange is proposing amendments that would extend the existing prepublication review and approval prohibition beyond investment banking personnel to anyone associated with the broker or dealer, other than research department personnel (*See* proposed NYSE Rule 472(b)(2) and (3)). In doing so, the Exchange is augmenting its existing rule prohibitions, which it believes is thus helping to foster a better climate for research analysts to produce unbiased research free of the conflicts that had beset the industry prior to the adoption of the SRO Rules last year.

Section 15D(a)(1)(C) of the Exchange Act requires ''that a broker or dealer and persons employed by such broker or dealer who are involved in investment banking activities may not, directly or indirectly retaliate against or threaten to retaliate against any securities analyst employed by that broker or dealer or its affiliates as a result of an adverse, negative or otherwise unfavorable research report that may adversely affect the present or prospective investment banking relationship of the broker or dealer with the issuer that is the subject of the research report.''[19]

NYSE believes that, although recently enacted NYSE Rule 472 amendments have, to some extent, already addressed this issue, proposed amendments will incorporate the substance of this requirement and extend it to ''public appearances'' as well (*See* proposed NYSE Rule 472(g)(2)). In this regard, the Exchange believes that NYSE Rule 472(b)(1) already prohibits research analysts from being under the supervision and control of an investment banking department, and thus limits, to some degree, the ability

[14] *See* Securities Exchange Act Release No. 47876 (May 15, 2003).

[15] *See* NYSE Information Memo No. 02–26, dated June 26, 2002, and NASD Notice to Members 02–39, dated July 2002.

[16] *See* Securities Exchange Act Release No. 47110 (December 31, 2002), 68 FR 826 (January 7, 2003) (SR–NYSE–2002–49; SR–NASD–2002–154) (''October 2002 Filing'').

[17] 15 U.S.C. 78o–6(a)(1)(A).

[18] *Id.*

[19] 15 U.S.C. 78o–6(a)(1)(C).

of such personnel directly to retaliate against research analysts. According to NYSE, it is generally established that ''control'' refers to the ability to ''hire, fire, reward and punish'' and, thus, prohibiting control of research analysts by an investment banking department limits such opportunities for retaliation.

Further, amendments filed pursuant to the October 2002 Filing that are pending with the SEC would provide for the review and approval of research analysts' compensation by a committee of the member or member organization that reports to its Board of Directors, or where the member or member organization has no Board of Directors, to a senior executive officer of the member or member organization. Such committee would be prohibited from having representatives from the member's or member organization's investment banking department serving on such a committee, and would thus foreclose opportunities for the investment banking department to retaliate against a research analyst by adversely impacting his or her compensation. According to NYSE, in conforming to the SOA's anti-retaliation requirement, the Exchange will expand upon the limitations already imposed and pending limitations on such conduct in NYSE Rule 472.

Section 15D(a)(2) of the Exchange Act imposes quiet periods (*e.g.*, prohibition against publishing or otherwise distributing research reports) on brokers or dealers who have participated, or are to participate in a public offering as underwriters or dealers.[20] Current SRO rules impose quiet periods on the issuance of research reports of 40-days for initial public offerings (''IPOs'') and 10 days for certain secondary offerings.[21] However, these prohibitions apply only to managers and co-managers of securities offerings. NYSE believes that the current SRO quiet periods exceed those provided for under the Federal securities laws.

According to NYSE, in enacting quiet periods that exceeded those currently prescribed under the Federal securities laws,[22] the Exchange was seeking to minimize incentives that managing underwriters, by virtue of their relationships with issuers, would have to reward such issuers for their underwriting business by publishing favorable research soon after the completion of a securities offering. As such, the Exchange believes that extended quiet periods would allow market forces to determine the price of the security in the after-market, regardless of research reports with favorable and potentially biased recommendations.

The proposed amendments impose a 25-day quiet period on underwriters and dealers who are not managers or co-managers of an issuer's IPO (*See* proposed NYSE Rule 472(f)(3)). In doing so, the Exchange will place limitations on the issuance of research reports on any and all distribution participants following an issuer's IPO. The Exchange believes that this will eliminate any possible or potential competitive disadvantage that managers and co-managers are subject to under the current NYSE rule provisions.

In proposing a shorter quiet period for such dealers and underwriters than what is provided for under NYSE Rule 472(f)(1), the Exchange recognizes that such distribution participants, do not, by virtue of their relationships and compensation arrangements with issuers, have the same incentives and opportunities to publish favorable research for such issuers as do managers and co-managers of such offerings. Accordingly, the NYSE believes that a 25-day quiet period is appropriate for such distribution participants. According to NYSE, the Exchange, along with the NASD, is proposing a uniform definition of the term ''offering date'' that will be applied to this new quiet period as well as to the existing ones (NYSE Rule 472(f)(1) and (2)) (*See* proposed NYSE Rule 472.120).

Further, section 15D(a)(2) of the Exchange Act utilizes the term ''publish or otherwise distribute'' in its rule text.[23] Accordingly, the Exchange is proposing to make conforming changes where applicable to its current rule provisions (*See* proposed NYSE Rules 472(b)(2) and (3), NYSE Rules 472(e)(2), (4)(ii) and (iv), (f)(1), (2) and (3)). In addition, the Exchange will be renumbering paragraphs 472(f)(3) through (5) as a result of the above changes.

Section 15D(b)(2) of the Exchange Act requires disclosure of ''whether *any compensation* has been received by a broker or dealer, or any affiliate thereof, including the securities analyst, from the issuer, that is the subject of the appearance or research report, subject to such exemptions as the Commission may determine appropriate and necessary to prevent disclosure of material non-public information regarding specific potential future investment banking transactions of such issuer.''[24]

Currently, Exchange Rule 472(k)(1)(ii)(b) requires that a member or member organization must disclose in research reports if the member or member organization or its affiliate has received compensation for investment banking services from a subject company in the past twelve (12) months. In addition to this required disclosure, proposed amendments would require disclosure in research reports of receipt of *any compensation,* other than for investment banking services, by a member or member organization from a subject company in the prior twelve (12) months (with no forward-looking provision) (*See* proposed NYSE Rule 472(k)(1)(iii)(c)).

According to NYSE, in requiring this additional disclosure, the Exchange recognizes that the receipt of any compensation, not just that resulting from investment banking services, may lend itself to the types of potential conflicts of interest between members and member organizations and their subject companies, that the initial rule amendments approved in the May 10th Order were promulgated to address, and thus in the interest of investor protection should be disclosed in research reports.

In addition, proposed NYSE Rule 472(k)(1)(ii) would require a research analyst (associated person) to disclose in public appearances (if such person knows or has reason to know) whether the member or member organization or any affiliate thereof, received any compensation from a subject company in the past twelve (12) months. Further, proposed NYSE Rule 472(k)(1)(i)(f) will require disclosure in a research report and public appearances of whether a research analyst (associated person) received any compensation from a subject company in the past twelve (12) months.

Although current NYSE Rules prohibit a research analyst from being compensated for specific investment banking services transactions (*See* NYSE Rule 472(h)(1)), and require disclosure in research reports of whether a research analyst received compensation, based in

[20] 15 U.S.C. 78o–6(a)(2).

[21] *See* NYSE Rule 472(f)(1), (2); NASD Rule 2711(f).

[22] Currently, Rule 174(d) under the Securities Act of 1933 (the ''Securities Act'') provides for a twenty-five (25)-day prospectus delivery requirement for an issuer's IPO if the security is to be listed on an exchange or authorized for inclusion in an interdealer quotation system such as Nasdaq. 17 CFR 230.174(d). The twenty-five (25)-day quiet period coincides with the twenty-five (25)-day prospectus delivery requirement under this rule. *See* Proposed NYSE Rule 472(f)(3). In addition, the restrictions regarding publication of research reports in Rule 101 of Regulation M do not apply to research reports that comply with Rules 138 or 139 (available to certain S–2 and/or S–3 issuers) under the Securities Act. 17 CFR 242.101(b)(1); 17 CFR 230.138; 17 CFR 230.139.

[23] 15 U.S.C. 78o–6(a)(2).

[24] 15 U.S.C. 78o–6(b)(2).

part on a member's or member organization's investment banking revenue (*See* NYSE Rule 472(k)(2)), the breadth of the new proposed rule requirement is greater in that it would require disclosure of the receipt of any compensation received by a research analyst from the subject company. According to NYSE, the potential for conflicts of interest between a member, member organization, or its research analyst, and a subject company can exist irrespective of the type of compensation received from the subject company. The NYSE believes that the proposed rule requirement will better address this potential conflict by requiring disclosure of any compensation that might possibly compromise a firm, its analyst, and the issuance of a research report on such subject company.

Further, the NYSE believes that the proposed new disclosure requirements are also in keeping with the spirit of the Commission's recently enacted Regulation Analyst Certification (''Regulation AC''),[25] which requires, if applicable, that a research analyst in a research report attest that ''part or all of the research analyst's compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed by the research analyst in the research report,'' and ''further disclosing that the compensation could influence the recommendations or views expressed by the research report.''[26] As proposed, the Exchange believes that the new disclosure requirements would better enable public investors to determine whether such recommendations made in research reports and during public appearances could have been influenced by the receipt of compensation by the research analyst and his or her member or member organization.

Section 15D(b)(3) of the Exchange Act requires disclosure of ''whether an issuer, whose securities are recommended in a public appearance or research report, currently is, or was, during the 1-year period preceding the appearance or date of distribution of the research report, a client of the broker or dealer, and if so, * * * [a statement of] the type of services provided to the issuer.''[27] Currently, NYSE Rule 472(k)(1)(ii) requires a research analyst (associated person) to disclose during a public appearance (when such person knows or has reason to know) if a subject company is an investment banking services client of the member or member organization.

According to NYSE, the proposed amendments will provide for disclosure by a member or member organization in research reports and a research analyst (associated person) during a public appearance, of whether a subject company is a client of the member or member organization, and the types of services provided to the client (*See* proposed NYSE Rule 472(k)(1)(i)(c)).

The types of services have been categorized into: investment banking services (which are currently required to be disclosed under NYSE Rule 472(k)(1)(ii)(a)); non-investment banking-securities related services; and non-securities services (*See* proposed NYSE Rule 472(k)(1)(i)(c.).

The Exchange believes that requiring disclosure of whether a subject company is a client and the types of services provided, and not merely an investment banking client of a member or member organization, should provide investors with potentially more meaningful insight into the nature of the relationship between the subject company and the member or member organization and the potential conflicts attendant to such relationships. For example, the Exchange believes that it might be more beneficial for an investor, in determining whether a firm has real conflicts of interest inherent in conducting investment banking on behalf of a subject company, to know that a member or member organization is actually providing non-investment banking securities related services to a subject company, such as conducting a share-buy-back for such company, rather than a securities underwriting.

In requiring that firms and their research analysts enumerate the types of services provided to subject companies, the Exchange recognizes that there is a possibility that this could result in the tipping of material non-public information. This issue was raised with the prior rule amendments, which require disclosure of prospective investment banking compensation (*See* NYSE Rule 472(k)(1)(ii)(c)). According to NYSE, in this regard, the SROs had defined investment banking services broadly enough to mitigate the issue of tipping material non-public information. The Exchange believes that it has also addressed this issue with the proposed new disclosure requirements. As proposed, the rule provides for an exemption from the disclosure requirements of proposed NYSE Rule 472(k)(1)(i)(c) and NYSE Rule 472(k)(1)(iii)(b) and (d)[28] to the extent that such disclosure would reveal material non-public information regarding specific potential future investment banking services transactions of the subject company (*See* proposed NYSE Rule 472(k)(1)(iv)).

The Exchange is proposing to amend NYSE Rule 472(k)(1)(iii)(a),[29] which requires a member or member organization or its affiliate to disclose in a research report if it has managed or co-managed a public offering of equity securities for a subject company in the past twelve (12) months, by deleting the word ''equity'' from the rule text. According to NYSE, the purpose of the proposed amendment is to make the Exchange's rule language consistent with the comparable NASD rule provision. As proposed, members and member organizations would be required to make such disclosures if they participated in debt offerings for a subject company as well. In amending this disclosure requirement, the Exchange recognizes that the same potential conflicts of interest exist, regardless of the type of security offering conducted by a member or member organization on behalf of a subject company.

Print Media Disclosures

As noted above, amendments currently pending with the SEC expand the definition of ''public appearance'' to include associated persons (research analysts) making a recommendation in a newspaper article or similar public medium thereby requiring such persons to make the same disclosures (*e.g.*, whether the associated person has a financial interest in and/or is an officer or director of the subject company) that are required in other public appearances (*e.g.*, TV broadcasts).

The Exchange received comments from representatives of the print media industry that extending the definition of ''public appearance'' to include print media would, in their view, infringe upon their First Amendment rights in view of the fact that the Exchange has interpreted NYSE Rule 472 to require research analysts to refrain from continued contacts with media outlets that have failed to publish or have

[25] *See* Securities Exchange Act Release No. 47384 (February 20, 2003), 68 FR 9482 (February 27, 2003).

[26] 17 CFR 242.501.

[27] 15 U.S.C. 78o–6(b)(3).

[28] NYSE Rule 472(k)(1)(iii)(b) and (d), were approved, as part of the original amendments as NYSE Rule 472(k)(1)(ii)(b) and (c). Both provisions have been renumbered as part of NYSE Amendment No. 2.

[29] NYSE Rule 472(k)(1)(iii)(a), was approved, as part of the original amendments as NYSE Rule 472(k)(1)(ii)(a). This provision has been renumbered as part of NYSE Amendment No. 2.

edited out the disclosures required by the Rule.[30]

After consideration of comments, the Exchange proposes to address this issue by providing written interpretive guidance that is hereby filed with the SEC as a proposed rule change. The proposed interpretation would require a research analyst (associated person) that recommends securities in a print media interview, newspaper article prepared under his or her name, or broadcast, to maintain a record of such interview, article, or broadcast. Such record must contain pertinent information regarding the event and the required disclosures provided to the media source. Further, such record must be made regardless of whether the media outlet publishes or broadcasts the required disclosures. In addition, records of such interviews, articles, or broadcasts and the requisite disclosures must be made in accordance with Rules 17a–3 and 17a–4 under the Exchange Act.[31]

The proposed interpretation would not require a research analyst (associated person) to refrain from further interviews, articles or broadcasts if the media source failed to publish or broadcast the required disclosures, provided the research analyst (associated person) had provided the required disclosures to the media source.

Small Firm Exemption

Currently NYSE Rules 472(b)(1), (2) and (3) (the gatekeeper provisions) prohibit ''associated persons,'' as defined in NYSE Rule 472.40, from being subject to the supervision or control of any employees of a member's or member organization's investment banking department, and further require legal or compliance personnel to intermediate certain communications between the research department and either the investment banking department or the company that is the subject of a research report by the research department. As noted above, the SEC approved exemptions from the gatekeeper provisions for small firms, on a temporary basis.[32] The Exchange is proposing that certain elements of the temporary small firm exemption to the gatekeeper provisions of NYSE Rules 472(b)(1), (2) and (3) be made permanent.[33] Those members and member organizations that meet the requirements for the small firm permanent exemption would still be required to maintain records of communications that would otherwise be subject to the gatekeeper provisions of NYSE Rules 472(b)(3)(i) and (ii). According to NYSE, proposed new NYSE Rule 472(m) would conform NYSE rules to the NASD proposal.

Implementation Schedule/Effective Dates

The Exchange is requesting the following implementation schedule for the proposed amendments being made in accordance with the SOA (all time periods commence on the date that the SEC approves the amendments) in order for members and member organizations to have adequate lead time to develop and implement procedures necessary to comply with the additional requirements of the rules.[34]

- NYSE Rules 472(k)(1)(i)(c), (k)(1)(ii), (k)(1)(iii)(c), and (k)(1)(iv) (except as it pertains to Rule 472(k)(1)(iii)(b) and (d), effective immediately upon approval))—Compensation and Client Disclosure Provisions—120 days
- NYSE Rules 472(g)(2) and 472(m)—Anti-Retaliation and Small Firm Exemption Provisions—effective immediately upon approval
- All other Rule provisions—60 days

2. NYSE's Statutory Basis

The Exchange believes that the statutory basis for the proposed rule change is section 6(b)(5) of the Exchange Act,[35] which requires, among other things, that the rules of the Exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade and in general to protect investors and the public interest.

3. NASD's Purpose

In the October 2002 Filing, NASD proposed a rule change to further improve the quality and objectivity of research and provide investors with better information to make their investment decisions. Generally, the proposed rule change would effectuate the following: further separate analyst compensation from investment banking influence; prohibit analysts from issuing ''booster shot'' research reports; extend to public appearances quiet periods on research issued by underwriting managers and co-managers; prohibit analysts from issuing research where they participated in solicitation of the issuer to be an underwriter for the issuer's initial public offering; require members to publish a final research report when they terminate coverage of a subject company; change the definitions of research analyst and research report; impose registration, qualification and continuing education requirements on research analysts; and certain other changes.

According to NASD, NASD Amendment No. 2 implements provisions of the SOA regarding securities analysts. The SOA, which amends section 15 of the Exchange Act,[36] requires either the SEC or a registered securities association to enact by July 30, 2003 rules reasonably designed to address conflicts of interest that can arise when securities analysts recommend equity securities in research reports and public appearances. The SOA further sets forth certain specific rules that must be promulgated. According to NASD, NASD Amendment No. 2 would implement those specific rules that are not already contained in current NASD Rule 2711 or the pending rule change proposals that were published in the Original Notice.

NASD Amendment No. 2 also would create an exemption from certain provisions of NASD Rule 2711 for smaller firms that engage in limited underwriting activity. Finally, NASD Amendment No. 2 would make certain other changes to clarify language in current or proposed rules or conform language to that used in the SOA. The proposed changes are explained in more detail below.

Restrictions on Relationships With the Research Department

Section 15D(a)(1)(A)[37] of the Exchange Act restricts prepublication clearance or approval of research reports by persons not directly responsible for investment research, other than legal or compliance staff. NASD Rule 2711(b) already bans review and approval by investment banking personnel. NASD Amendment No. 2 would extend the prohibition to other non-research personnel and also require that communications about the content of a research report between all non-research

[30] *See* Letters to Jonathan G. Katz, Secretary, Commission from: Bloomberg News, dated February 19, 2003; Securities Industry Association, dated March 10, 2003; and Newspaper Association of America, dated March 10, 2003.

[31] 17 CFR 240.17a–3 and 17 CFR 240.17a–4.

[32] *See* note 13 *supra.*

[33] The Exchange is not proposing to exempt these members and member organizations from NYSE Rule 472(b)(4), which restricts communications between the research department and the subject company, because the Exchange believes that those communications do not result in the same burdens as NYSE Rules 472(b)(1), (2), and (3). NYSE Rule 472(b)(1), (2), and (3) were approved as part of the original amendments. NYSE Rule 472(b)(3) has been renumbered as part of NYSE Amendment No. 2 as NYSE 472(b)(4).

[34] *See* NYSE Amendment No. 1 for proposed implementation dates for amendments pending with the Commission.

[35] 15 U.S.C. 78f(b)(5).

[36] *See* note 8 *supra.*

[37] 15 U.S.C. 78o–6(a)(1)(A).

personnel and the research department be intermediated by legal or compliance staff.

Quiet Periods

Section 15D(a)(2)[38] of the Exchange Act requires establishment of periods during which brokers or dealers who have participated or are to participate in a public securities offering as underwriters *or dealers* may not publish or otherwise distribute research reports related to the issuer of the offering. NASD Rule 2711(f) currently imposes such quiet periods—for 40 calendar days following an initial public offering and 10 calendar days following a secondary offering—on underwriting managers and co-managers, but not on other members of the underwriting syndicate or selling group. According to NASD, to comply with the SOA, NASD Amendment No. 2 would establish a 25-day period after the ''date of the offering'' during which an underwriter or dealer other than a manager or co-manager would be prohibited from publishing or distributing research on the issuing company's securities. This 25-day prohibition effectively codifies a *de facto* quiet period that exists because of the prospectus delivery requirements under Rule 174 under the Securities Act.[39] In general, brokers or dealers refrain from issuing research on exchange-listed or National Market System securities for 25 days after a registration statement becomes effective or bona fide public trading begins to avoid the risk that such communications may be deemed prospectuses that do not meet the requirements of section 10 of the Securities Act.[40]

NASD Amendment No. 2 also would define ''date of the offering'' for all quiet period provisions to mean the later of the effective date of the registration statement or the first date on which the security was bona fide offered to public.

Prohibition of Retaliation Against Research Analysts

Section 15D(a)(1)(C)[41] of the Exchange Act prohibits a broker or dealer engaged in investment banking activities from directly or indirectly retaliating, or threatening to retaliate, against a research analyst who publishes a research report that may adversely affect a member's present or prospective investment banking relationship. NASD Amendment No. 2 creates new NASD Rule 2711(j) to implement this directive and extends the prohibition to public appearances. The proposed rule incorporates language in SOA that clarifies that the prohibition does not limit a member's authority to discipline a research analyst, in accordance with the member's policies and procedures, for any cause other than writing a research report or the making of a public appearance that is unfavorable to a current or potential investment banking relationship. NASD has further clarified in the proposal that the anti-retaliation provision would not preclude termination, in accordance with firm policies and procedures, for causes unrelated to issuing or distributing such adverse research or for making an unfavorable public appearance regarding a current or potential investment banking relationship.

Receipt of Compensation and Disclosure of Client Relationships

Section 15D(b)(2)[42] of the Exchange Act requires disclosure by a broker or dealer in research reports, and by a research analyst in public appearances, if any compensation has been received by the broker or dealer, or any affiliate thereof (including the analyst), from the issuer that is the subject of the report or public appearance. Section 15D(b)(3)[43] of the Exchange Act further requires disclosure if the subject issuer is, or has been during the previous year, a client of the broker dealer, and if so, the types of services provided to the issuer. Section 15D(b)(2)[44] of the Exchange Act is subject to exemptions as the Commission may determine appropriate and necessary to prevent disclosure of material non-public information regarding specific potential future investment banking transactions of the issuer.[45]

According to NASD, these mandates necessitate several changes to current NASD Rule 2711. First, NASD Rule 2711 currently requires disclosure only of investment banking compensation received from a subject company or its affiliates in the past 12 months. Accordingly, NASD Amendment No. 2 would expand the required disclosure to cover any compensation received by a member or its affiliates from the subject company. While the SOA does not specify a look-back period, NASD has established a 12-month retrospective period to be consistent with existing NASD Rule 2711 and section 15D(b)(3)[46] of the Exchange Act, which imposes the same timeframe for disclosure of a client relationship with the subject company.

NASD Amendment No. 2 would require separate disclosure of investment banking compensation and other, non-investment banking compensation received from the subject company or its affiliates. NASD believes this approach will result in more meaningful disclosure by separating out investment banking compensation, which NASD believes generally is the primary influence on research objectivity. Absent the separate disclosure, investors might not learn whether disclosure of compensation received by the member from the subject company came from lucrative Investment banking services or less remunerative and influential business lines. NASD specifically requests comment on whether a *de minimis* exemption would be appropriate for this provision, and if so, at what dollar level such exemption should be set.

Second, NASD Rule 2711 currently does not expressly require disclosure of compensation received by a research analyst from a subject company. To the extent that receipt of such compensation constitutes an actual, material conflict of interest, disclosure would be required under NASD Rule 2711(h)(1)(C). Nonetheless, NASD is amending NASD Rule 2711 to require disclosure of any compensation received by an analyst from the subject company in the past 12 months.

Third, NASD is amending NASD Rule 2711 to add a provision that requires a research analyst to disclose in public appearances if the member or any of its affiliates received any compensation from the subject company within the past 12 months. A research analyst must only disclose this fact if the analyst knows or has reason to know it to be the case.

Fourth, NASD is amending NASD Rule 2711 to require disclosure in research reports and public appearances if the subject company is, or has been over the preceding 12 months, a client of the member. If this disclosure is applicable, the member (in research reports) or the research analyst in public appearances (if the research analyst knows or has reason to know) must also disclose the types of client services provided to the subject company. These services may be described as falling into

[38] 15 U.S.C. 78o–6(a)(2).

[39] 17 CFR 230.174.

[40] 15 U.S.C. 77j.

[41] 15 U.S.C. 78o–6(a)(1)(C).

[42] 15 U.S.C. 78o–6(b)(2).

[43] 15 U.S.C. 78o–6(b)(3).

[44] 15 U.S.C. 78o–6(b)(2).

[45] The exemptive language of the SOA appears only in section 15D(b)(2) of the Exchange Act (15 U.S.C. 78o–6(b)(2)). However, NASD and the staff of the Exchange believe that the exemption must be interpreted to apply to certain other disclosure requirements that could tip material non-public information regarding a specific potential future investment banking transaction or else the purpose of the exemption would be frustrated.

[46] 15 U.S.C. 78o–6(b)(3).

one of the following three categories: (1) Investment banking services, (2) non-investment banking securities-related services, or (3) non-securities services.

Small Firm Exemption

NASD Amendment No. 2 also would create new NASD Rule 2711(k), an exemption from NASD Rule 2711(b) for certain firms that engage in limited underwriting activity. NASD Rule 2711(b) prohibits a research analyst from being subject to the supervision or control of any employee of a member's investment banking department and further requires legal or compliance personnel to intermediate certain communications between the research department and the investment banking department.

As the Commission noted in the May 10th Order, several commenters argued that the gatekeeper provisions of NASD Rules 2711(b) and (c) would impose significant costs, especially for smaller firms that would have to hire additional personnel. Commenters also noted that personnel often wear multiple hats in smaller firms, thereby causing a greater burden to comply with the restriction on supervision and control by investment banking personnel over research analysts. These comments raised the prospect that the rules might force some firms out of business or reduce important sources of capital and research coverage for smaller companies and companies of regional or local interest.

To temporarily address those concerns while it considered an appropriate exemption, NASD delayed effectiveness of NASD Rules 2711(b) and (c) until July 30, 2003, or until a superseding permanent exemption is approved by the SEC and becomes effective, for those members that over the previous three years, on average per year, have participated in 10 or fewer investment banking transactions or underwritings as manager or co-manager and generated $5 million or less in gross investment banking revenues from those transactions.[47] NASD Amendment No. 2 would create a permanent exemption from NASD Rule 2711(b) for those members that meet the same eligibility requirements as was required for the temporary exemption. NASD is not proposing to exempt these members from NASD Rule 2711(c), which restricts communications between the research department and the issuer, because NASD believes those communications do not result in the same burdens as NASD Rule 2711(b).

NASD Amendment No. 2 also would require members that qualify for this exemption to maintain records for three years of any communication that otherwise would be subject to the review and monitoring provisions of NASD Rule 2711(b)(3).

Other Changes

NASD Amendment No. 2 also would conform certain existing rule language with that used in the SOA. For example, the term ''publish or otherwise distribute'' has been substituted in place of references to research reports that are ''issued'' or ''published.'' The amendment also would make a few other non-substantive language changes.

Effective Dates

NASD suggests the following effective dates for the new provisions contained in SR–NASD–2002–154 and this Amendment thereto:

- NASD Rule 1050—Registration of Research Analysts: such time as announced in a *Notice to Members* after SEC approval of the rule change, but not less than 180 days from such approval
- NASD Rule 1120(a)(5) and (b)(1)—Regulatory and Firm Elements: Not less than 180 days after SEC approval of the rule change
- NASD Rule 2711(h)(2)(C)—Disclosure of Non-Investment Banking Compensation: 120 days after SEC approval of the rule change
- NASD Rule 2711(h)(2)(E)—Disclosure in Public Appearances of Compensation Received from Issuer and Affiliates: 120 days after SEC approval of the rule change
- NASD Rule 2711(h)(2)(F)—Disclosure of Client Relationship and Types of Services: 120 days after SEC approval of the rule change
- NASD Rule 2711(h)(2)(G)—Exemption from Disclosure Requirements:

—As applied to disclosures under NASD Rules 2711(h)(2)(B)(ii) and (iii): Immediate upon SEC approval of the rule change

—As applied to disclosures under NASD Rule 2711(h)(2)(F): 120 days after SEC approval of the rule change

- NASD Rule 2711(j)—Prohibition of Retaliation Against Research Analysts: Immediate upon SEC approval of the rule change
- NASD Rule 2711(k)—Small Firm Exemption: Immediate upon SEC approval of the rule change
- All other provisions: 60 days after SEC approval of the rule change

4. NASD's Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Exchange Act,[48] which requires, among other things, that NASD's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD believes that this proposed rule change will reduce or expose conflicts of interest and thereby significantly curtail the potential for fraudulent and manipulative acts. NASD further believes that the proposed rule change will provide investors with better and more reliable information with which to make investment decisions.

B. Self-Regulatory Organizations' Statements on Burden on Competition

The NYSE and the NASD do not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act, as amended.

C. Self-Regulatory Organizations' Statements on Comments on the Proposed Rule Changes Received From Members, Participants or Others

The NYSE and NASD have neither solicited nor received written comments on the proposed rule changes. Comments received by the SEC in response to the Original Notice will be addressed together with comments received after publication of NYSE Amendment No. 2 and NASD Amendment No. 2.

III. Date of Effectiveness of the Proposed Rule Changes 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 Exchange consents,[49] the Commission:

[47] *See* Securities Exchange Act Release No. 47876 (May 15, 2003); *See also* Securities Exchange Act Release No. 46165 (July 3, 2002), 67 FR 46555 (July 15, 2002).

[48] 15 U.S.C. 78o–3(b)(6).

[49] *See* Letters to James Brigagliano, Assistant Director, Trading Practices, Division, Commission from: Darla Stuckey, Corporate Secretary, NYSE, consenting to an extension of the statutory time under section 19(b)(2) of the Exchange Act, until the Commission takes action on Rule filing SR–NYSE–2002–49 (December 27, 2002); and Philip Shaikun, Assistant General Counsel, NASD consenting to an extension of the statutory time under section 19(b)(2) of the Exchange Act, until the Commission takes action on Rule filing SR–NASD–2002–154 (December 27, 2003).

(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 NYSE Amendment No. 2 and NASD Amendment No. 2, including whether the amendments are consistent with the Exchange Act and whether there are any differences between the NYSE and NASD proposals that present compliance or interpretive issues.

On April 28, 2003, Commission Chairman William H. Donaldson, NASD Chairman and CEO Robert Glauber, NYSE Chairman and CEO Richard Grasso, and other regulators, announced the completion of enforcement actions against a number of the nation's largest investment banking firms.[50] The enforcement actions finalized a settlement in principle reached and announced by regulators last December.[51] The settlement followed joint investigations by the regulators of allegations of undue influence of investment banking interests on securities research at brokerage firms. The Commission notes that certain elements of the settlement cover areas addressed by the SROs in the Original Notice; however, the requirements are not identical. In light of the settlement, the Commission solicits additional comment on the NYSE and NASD rule changes that were proposed in the Original Notice.

In addition, the Commission specifically solicits comment on proposed NASD 2711(k) and proposed NYSE 472(m), which address small firms. In particular, the Commission requests comment on whether the proposed thresholds for the small firm exception are appropriate (ten or fewer investment banking services transactions as manager or co-manager and $5 million or less in gross investment banking revenues from those transactions). Should the $5 million limit apply to gross revenues from all investment banking services transactions rather than only to those for which the firm acted as manager or co-manager?

The Commission notes that, in addition to proposing rules to meet the requirements of the SOA and the small firm exception, in NYSE Amendment No. 2 the Exchange also proposed an Interpretation relating to public appearances and the print media that would require members to make and keep records of information relating to public appearances. The NASD has not included a similar record-keeping requirement in NASD Amendment No. 2. The Commission requests comment on whether this record-keeping requirement is appropriate, and whether both SROs should adopt such a requirement.

Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule changes that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room in 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of such filing will also be available for inspection and copying at the principal offices of the SROs. All submissions should refer to File Nos. SR–NYSE–2002–49 and SR–NASD–2002–154 and should be submitted by June 19, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[52]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–13446 Filed 5–28–03; 8:45 am]

BILLING CODE 8010–01–P

[50] SEC Press Release No. 2003–54 (April 28, 2003).

[51] SEC Press Release No. 2002–179 (December 20, 2002).

[52] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47898; File No. SR–OCC–2002–11]

Self-Regulatory Organizations; the Options Clearing Corporation; Order Approving Proposed Rule Changes To Modify the Stock/Loan Hedge Program

May 21, 2003.

I. Introduction

On May 21, 2002, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') and on July 16 and September 26, 2002, amended proposed rule change SR–OCC–2002–11 pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'').[1] Notice of the proposal was published in the **Federal Register** on March 4, 2003.[2] For the reasons discussed below, the Commission is approving the proposed rule changes.

II. Description

The purpose of the proposed rule change is to modify OCC's Hedge Program, under which OCC operates a centralized facility for clearing stock loan/borrow transactions between OCC clearing members. In order to provide enhanced risk management while maintaining the flexibility of the current program, OCC proposes to establish: (i) Heightened financial requirements as a condition for clearing members to designate accounts as margin-ineligible; (ii) additional eligibility requirements for eligible securities; and (iii) limits on the notional value of the stock loan/borrow position that a clearing member may maintain in a single stock in a margin-ineligible account.

OCC's Hedge Program is intended to facilitate stock lending transactions among OCC's clearing members. Clearing members effecting stock loan/borrow transactions through the Hedge Program obtain the advantages of centralized clearing of those transactions as well as reduced credit risk through the substitution of OCC as the counterparty in all transactions. Unless a clearing member has designated an account as margin-ineligible for purposes of the Hedge Program, stock loan and borrow positions are margined by OCC's TIMS[3] margin system using the same basic risk assessment procedures that are used for positions in options or futures. For many clearing members, this results in an important advantage of the Hedge Program. By taking into consideration the reduction in risk where stock loan/borrow positions are on the opposite side of the market from option positions on the same underlying stock, the margin system will calculate a reduced margin requirement for the account containing the offsetting positions.[4]

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 47402 (February 25, 2003), 68 FR 10291.

[3] The Theoretical Intermarket Margin System, known as TIMS, uses advanced portfolio theory to recognize economically and statistically reasonable hedges among various positions and to correctly assess the dollar risk of those positions.

[4] While similar offset may exist between positions in index options and a group of stock loan/borrow positions that are identified as baskets comprised of constituent securities in the index, the stock borrow basket/stock loan basket feature of the Hedge Program, although provided for in the OCC By-Laws and Rules, has not been placed into operation for

For other clearing members, however, the margin offset or hedging aspect of the Hedge Program is of little or no benefit. For these clearing members, the nature of their business is such that they rarely if ever have stock loan/borrow transactions that provide any significant offset against their options positions. These clearing members may nevertheless desire to use the Hedge Program because of its other benefits. The participation of these clearing members, which tend to be the larger clearing members, is desirable from OCC's perspective because they contribute liquidity to the program and facilitate the hedging activity of some of OCC's less well-capitalized clearing members.

For those clearing members whose stock loan/borrow positions are not ordinarily offset by options positions, clearing stock loan/borrow activity through the Hedge Program increases rather than reduces their risk margin requirement at OCC. In the stock loan market, collateral (usually equal to 100% or 102% of the value of the loaned stock) is provided by the borrower to the lender to secure the lender's obligation to return the stock. Daily mark-to-market payments between the borrower and lender maintain the collateral at that level. The same is true when stock loan activity is cleared through the Hedge Program. However, in addition to the collateral that is passed by OCC between the borrowing and lending clearing members, OCC's TIMS system also assesses both the borrower and the lender an amount of risk margin equal to one day's anticipated maximum market movement in order to protect OCC against a default by the borrower or the lender in its mark-to-market obligations. Because this risk margin is collected only for stock loan transactions that are submitted to OCC, clearing these transactions through OCC imposes additional costs on some clearing members.

In order to address this issue, the Hedge Program permits clearing members to elect to carry stock loan and borrow transactions on a margin-ineligible basis. If a clearing member designates an account as margin-ineligible, OCC will exclude any stock loan or borrow positions in that account when calculating the regular margin requirement for the account. OCC, however, relies on other elements of its protection systems [5] to assess its potential exposure with respect to positions carried in a margin-ineligible account.[6]

OCC believes that permitting clearing members to carry stock loan and borrow positions on a margin-ineligible basis is appropriate, safe, and essential to the competitiveness of the Hedge Program. However, in recognition of the fact that this alternative does create uncollateralized risk for OCC, OCC has conducted a study of credit practices in the stock loan market generally and has determined to implement certain measures to reduce its risk.

Although OCC's current risk management practices are consistent with industry standards, OCC is nevertheless adopting elevated financial standards for clearing members wishing to designate accounts as margin-ineligible for purposes of the Hedge Program. Clearing members would be required to maintain excess net capital of at least $75 million in order to carry margin-ineligible accounts with OCC.[7] OCC believes this requirement is sufficient to ensure strong participant credit standing without unduly hindering program participation.

The excess net capital requirement would be supplemented by a profitability standard. A clearing member will not be permitted to maintain a margin-ineligible account if it has: (i) Losses in one month equal to or exceeding 50 percent of its excess net capital; (ii) cumulative losses over two consecutive months equal to or exceeding 60 percent of its excess net capital; or (iii) cumulative losses over three consecutive months equal to or exceeding 70 percent of its excess net capital. These excess net capital and profitability standards will be ongoing tests and will have to be met at all times by a clearing member wishing to carry stock loan or borrow positions in any account on a margin-ineligible basis. Clearing members falling out of compliance with these standards will be precluded from clearing opening transactions in a margin-ineligible account while out of compliance.

The rationale for these requirements is that unlike a participant in the regular stock loan market, which has the ability to consider the impact of new transactions on counterparty credit limits before entering into them, OCC becomes a counterparty solely at the discretion of the lender and borrower without the ability to approve or disapprove individual loans on a credit basis before they are accepted for clearance. OCC's excess net capital and profitability standards should substitute for a transaction-by-transaction credit review. Using these straightforward requirements instead of a credit limit or activity cap makes it unnecessary for OCC to reserve the right to reject completed transactions in cases where acceptance would put one of the parties above its cap.

As an additional safety measure, OCC is amending the definition of ''eligible stock'' to exclude non-option stocks from the program subject to limited exceptions.[8] Loans for non-option stocks will be permitted to be maintained (i) if the loan was accepted prior to the implementation of the restriction or (ii) if the stock is deliverable upon exercise of an outstanding option (*e.g.*, where a stock ceases to be an option stock but options on that stock remain outstanding or where a non-option stock is distributed to holders of an option stock and options on the latter are adjusted to require delivery of both stocks). The restriction applies only to non-option stocks because OCC does not want to limit clearing members' ability to include option hedging transactions in their accounts.

Finally, no lender or borrower will be allowed to maintain a stock loan or borrow position in a single issue in a margin-ineligible account if the notional value of the position exceeds the clearing member's excess net capital. This restriction is intended to address concentration risk. Where the positions are carried in a margin-eligible account, the restriction is deemed unnecessary because OCC will hold collateral sufficient to cover the risk.

systems reasons. OCC is proposing in this filing to add an interpretation following Section 2 of Article XXI of the By-Laws stating that OCC will provide notice to its clearing members when this feature becomes operative.

[5] OCC especially relies on its concentration monitoring system, known as ConMon, which provides a comparison of the capital and net worth of each OCC clearing member to the market risk associated with the clearing member's positions. Securities Exchange Act Release No. 40083 (June 11, 1998), 63 FR 33424 (June 18, 1998) [File No. SR–OCC–98–3].

[6] For example, margin will be required for positions carried in a margin-ineligible account if predefined concentration monitoring parameters are exceeded.

[7] Clearing members currently maintaining margin-ineligible accounts would be given a one-year grace period in which to conform to the minimum excess net capital requirement. If a clearing member is not in compliance at the end of that period, OCC would thereafter treat all of the clearing member's accounts as margin-eligible.

[8] As originally filed, the proposed rule change sought to amend the definition of ''eligible stock'' to require that non-option stocks that are the subject of program transactions have a price per share of at least $10.00 at the time the transaction is submitted to clearance. The September 26, 2002, amendment excludes non-option stocks from the program subject to limited exceptions in order to more closely align the use of the Hedge Program with its primary objective of recognizing the intermarket hedges between a participant's stock and options positions.

III. Discussion

Section 17A(b)(3)(F) of the Act requires that the rules of a clearing agency be designed to assure the safeguarding of securities and funds which are in its custody or control or for which it is responsible.[9] The Commission finds that OCC's proposed rule change is consistent with this requirement because the elevated net capital requirement, the loss limitation standards, the restriction on non-option stocks, and the concentration limitation have been designed to provide enhanced risk management of OCC risks resulting from clearing members carrying stock loan/stock borrow positions in margin-ineligible accounts.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (File No. SR–OCC–2002–11) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–13450 Filed 5–28–03; 8:45 am]

BILLING CODE 8010–01–P

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3492, Amdt. 2]

State of Mississippi

In accordance with a notice received from the Department of Homeland Security—Federal Emergency Management Agency, effective May 19, 2003, the above numbered declaration is hereby amended to include Pearl River and Marion Counties as disaster areas due to damages caused by severe storms, tornadoes and flooding beginning on April 6 and continuing through April 25, 2003.

In addition, applications for economic injury loans from small businesses located in the contiguous counties of Forrest, Lamar, Hancock, Harrison and Stone in the State of Mississippi; and St. Tammany Parish in the State of Louisiana may be filed until the specified date at the previously designated location. All other counties contiguous to the above named primary counties have been previously declared.

All other information remains the same, *i.e.*, the deadline for filing applications for physical damage is June 23, 2003, and for economic injury the deadline is January 26, 2004.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: May 21, 2003.

Cheri C. Wolff,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 03–13280 Filed 5–28–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3498, Amdt. 2]

State of Tennessee

In accordance with a notice received from the Department of Homeland Security—Federal Emergency Management Agency, effective May 19, 2003, the above numbered declaration is hereby amended to include Hardin, Morgan and Sumner Counties in the State of Tennessee as disaster areas due to damages caused by severe storms, tornadoes and flooding occurring on May 4, 2003, and continuing.

In addition, applications for economic injury loans from small businesses located in the contiguous counties of Anderson, Fentress, Macon and Scott in the State of Tennessee; Allen County in the State of Kentucky; and Tishomingo County in the State of Mississippi may be filed until the specified date at the previously designated location. All other counties contiguous to the above named primary counties have been previously declared.

All other information remains the same, *i.e.*, the deadline for filing applications for physical damage is July 7, 2003, and for economic injury the deadline is February 6, 2004.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: May 21, 2003.

Cheri C. Wolff,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 03–13279 Filed 5–28–03; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Privacy Act of 1974 as Amended; Computer Matching Program (SSA/Internal Revenue Service (IRS) Match Number 1016)

AGENCY: Social Security Administration (SSA).

ACTION: Notice of the renewal of an existing computer matching program, which is scheduled to expire on June 30, 2003.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces the renewal of an existing computer matching program that SSA is currently conducting with the IRS.

DATES: IRS will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate, the Committee on Government Reform of the House of Representatives, and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The renewal of the matching program will be effective as indicated below.

ADDRESSES: Interested parties may comment on this notice by either telefax to (410) 965–8582 or writing to the Associate Commissioner, Office of Income Security Programs, 760 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: The Associate Commissioner for Income Security Programs as shown above.

SUPPLEMENTARY INFORMATION:

A. General

The Computer Matching and Privacy Protection Act of 1988 Public Law (Pub. L.) 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the manner in which computer matching involving Federal agencies could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records.

It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the Data Integrity Boards' approval of the match agreements;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Dated: May 2, 2003.

Martin H. Gerry,

Deputy Commissioner for Disability and Income Security Programs.

Notice of Computer Matching Program, Social Security Administration (SSA) With Internal Revenue Service (IRS)

A. Participating Agencies

SSA and IRS.

B. Purpose of the Matching Program

The purpose of this matching program is to establish conditions under which IRS agrees to disclose to SSA certain return information for use in verifying eligibility for, and/or the correct amount of, benefits provided under Title XVI of the Social Security Act to qualified aged, blind and disabled individuals, and federally administered supplementary payments of the type described in section 1616(a) of such Act (including payments pursuant to an agreement entered into under section 212(a) of Pub. L. 93–66, 87 Stat. 152).

C. Authority for Conducting the Matching Program

Section 6103(1)(7) of the Internal Revenue Code (26 U.S.C. 6103(1)(7)) authorizes the IRS to disclose return information with respect to unearned income to Federal, State, and local agencies administering certain benefit programs under the Social Security Act.

Section 1631(e)(1)(B) of the Social Security Act (42 U.S.C. 1383(e)(1)(B)) requires verification of Supplemental Security Income (SSI) eligibility and benefit amounts with independent or collateral sources.

D. Categories of Records and Individuals Covered by the Matching Program

SSA will provide the IRS with identifying information with respect to applicants for and recipients of benefits available under programs specified in this Agreement from the Supplemental Security Income Record and Special Veterans Benefit (SSR), SSA/OSR 60–0103, as published at 66 FR 11079 (February 21, 2001). IRS will extract return information with respect to unearned income from the Wage and Information Returns (IRP) Processing File, Treas/IRS 22.061, hereafter referred to as the Information Return Master File (IRMF), as published at 66 FR 63797 (December 10, 2001), through the Disclosure of Information to Federal, State and Local Agencies (DIFSLA) program.

E. Inclusive Dates of the Matching Program

The matching program will become effective no sooner than 40 days after notice of the matching program is sent to Congress and OMB, or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 03–13235 Filed 5–28–03; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34353]

Union Pacific Railroad Company—Trackage Rights Exemption—The Burlington Northern and Santa Fe Railway Company

The Burlington Northern and Santa Fe Railway Company (BNSF) has agreed to grant overhead trackage rights to Union Pacific Railroad Company (UP) over a BNSF line of railroad between BNSF milepost 42.9 near Paola, KS, and BNSF milepost 633.0 near Joe Jct., TX,[1] a distance of approximately 428.2 miles.[2]

The transaction was scheduled to be consummated on May 16, 2003.

The purpose of the trackage rights is to permit UP to use the BNSF trackage when UP's trackage is out of service for scheduled maintenance.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.-Lease and Operate*, 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If it contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34353 must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Robert T. Opal, 1416 Dodge Street, Room 830, Omaha, NE 68179.

Board decisions and notices are available on our website at *http://www.stb.dot.gov*.

Decided: May 21, 2003.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 03–13241 Filed 5–28–03; 8:45 am]

BILLING CODE 4915–00–P

[1] On May 9, 2003, UP and BNSF filed a petition for partial revocation of this class exemption in STB Finance Docket No. 34353 (Sub-No. 1), *Union Pacific Railroad Company—Trackage Rights Exemption—The Burlington Northern and Santa Fe Railway Company*, wherein UP and BNSF request that the Board permit the proposed overhead trackage rights arrangement described in the present proceeding to: (1) become effective on May 16, 2003, and expire on or about June 22, 2003, for northbound trains; and (2) become effective on August 4, 2003, and expire on or about October 16, 2003, for southbound trains. That petition will be addressed by the Board in a separate decision.

[2] UP indicates that the milepost designations of the end points do not reflect the actual length of the trackage rights segment, because the trackage includes portions of BNSF subdivisions that have noncontiguous designations.

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Salt Lake County, UT

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared to address operational, infrastructure, and geometrical deficiencies along Redwood Road from 10400 South to the Bangerter Highway in Salt Lake County, Utah.

FOR FURTHER INFORMATION CONTACT: Sandra Garcia, Project Development Engineer, FHWA, Utah Division, 2520 West 4700 South, Suite 9A, Salt Lake City, UT 84118, Telephone (801) 963–0182; or Lars Anderson, Utah Department of Transportation (UDOT), 2010 South 2760 West, Salt Lake City, UT 84104, Telephone (801) 887–3470.

SUPPLEMENTARY INFORMATION: The project was initiated in 2000 as an Environmental Assessment (EA). However, based on the preliminary findings of technical evaluations and public involvement activities conducted to date, FHWA, in cooperation with the UDOT, determined that an EIS will be prepared in accordance with the National Environmental Policy Act (NEPA). The proposed action is needed to provide for existing and projected traffic demand along a 4.2-mile segment of Redwood Road, from 10400 South to the Bangerter Highway, Salt Lake County, Utah. The proposed study intends to consider no-build (including transit and transportation system management), transportation demand management (TDM), and build alternatives to address the need for improvements along this corridor. Build alternatives will consider upgrading the existing facility from two lanes to five lanes. The limits for the build alternatives are expected to be Bangerter Highway as the southern terminus and 10400 South as the northern terminus.

A public action committee team (PACT) was established during the course of the initial EA process to encourage early public participation from interested parties. Letters describing the proposed action and soliciting comments will be sent to the appropriate Federal, State and local agencies, and to private organizations and citizens who have expressed interest in this project. A public scoping meeting will be held in June 2003, in Salt Lake County, Utah. Additionally, a public hearing will be held in accordance with Federal Highway regulations. Public notice will be published giving the time and place of the scoping meeting and hearing. The draft environmental document will be available for review and comment before the public hearing.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to FHWA at the address provided above. (Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: May 22, 2003.

Gregory S. Punske,

Environmental Program Manager, Utah Division, Federal Highway Administration, Salt Lake City, Utah.

[FR Doc. 03–13390 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket NHTSA–99–5087]

Rulemaking Program Meeting

AGENCY: National Highway Traffic Safety Administration (DOT).

ACTION: Notice of NHTSA Rulemaking Status Meeting.

SUMMARY: This notice announces a public meeting at which NHTSA will answer questions from the public and the automobile industry regarding the agency's vehicle regulatory program.

DATES: From the last notice, the date and location has changed for the NHTSA Rulemaking Status Meeting. The Agency's regular public meeting relating to its vehicle regulatory program will be held on Thursday, July 31, 2003, beginning at 9:45 a.m. and ending at approximately 12 p.m. at the Hilton Crystal City Ronald Reagan National Airport, 2399 Jefferson Davis Highway, Arlington, Virginia 22202. Questions relating to the vehicle regulatory program must be submitted in writing with a diskette (Microsoft Word) by Wednesday, July 2, 2003, to the address shown below or by e-mail. If sufficient time is available, questions received after July 2 may be answered at the meeting. The individual, group or company submitting a question(s) does not have to be present for the question(s) to be answered. A consolidated list of the questions submitted by July 31, 2003, and the issues to be discussed will be posted on NHTSA's web site (*www.nhtsa.dot.gov*) by Monday, July 28, 2003, and also will be available at the meeting. The agency will hold a second public meeting on July 31, devoted exclusively to a presentation of research and development programs. This meeting will begin at 1:30 p.m. and end at approximately 5 p.m. This meeting is described more fully in a separate announcement. The next NHTSA Public Meeting will take place on Thursday, November 20, 2003, at the Best Western Gateway International Hotel, Romulus, Michigan 48174.

ADDRESSES: Questions for the July 31, NHTSA Rulemaking Status Meeting, relating to the agency's vehicle regulatory program, should be submitted to Delia Lopez, NVS–100, National Highway Traffic Safety Administration, Room 5401, 400 Seventh Street, SW., Washington, DC 20590, Fax Number 202–366–4329, e-mail *dlopez@nhtsa.dot.gov.* The meeting will be held at the Hilton Crystal City, Ronald Reagan National Airport, 2399 Jefferson Davis Highway, Arlington, Virginia 22202. The telephone number is 703–418–6800. A shuttle runs to and from Ronald Reagan National Airport every 15 minutes, and the hotel is about two blocks from the rail/subway.

FOR FURTHER INFORMATION CONTACT: Delia Lopez, (202) 366–1810.

SUPPLEMENTARY INFORMATION: NHTSA holds regular public meetings to answer questions from the public and the regulated industries regarding the agency's vehicle regulatory program. Questions on aspects of the agency's research and development activities that relate directly to ongoing regulatory actions should be submitted, as in the past, to the agency's Rulemaking Office. Transcripts of these meetings will be available for public inspection in the DOT Docket in Washington, DC, within four weeks after the meeting. Copies of the transcript will then be available at ten cents a page, (length has varied from 80 to 150 pages) upon request to DOT Docket, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. The DOT Docket is open to the public from 10 a.m. to 5 p.m. The transcript may also be accessed electronically at *http://dms.dot.gov,* at docket NHTSA–99–5087. Questions to be answered at the public meeting should be organized

by categories to help us process the questions into an agenda form more efficiently.

Sample format:

I. Rulemaking
  A. Crash avoidance
  B. Crashworthiness
  C. Other Rulemakings
II. Consumer Information
III. Harmonization
IV. Miscellaneous

NHTSA will provide auxiliary aids to participants as necessary. Any person desiring assistance of ''auxiliary aids'' (*e.g.,* sign-language interpreter, telecommunications devices for deaf persons (TDDs), readers, taped texts, brailled materials, or large print materials and/or a magnifying device), please contact Delia Lopez on (202) 366–1810, by COB Monday, July 28, 2003.

Issued: May 21, 2003.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 03–13283 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–59–M

DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation Advisory Board; Notice of Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. I) notice is hereby given of a meeting of the Advisory Board of the Saint Lawrence Seaway Development Corporation (SLSDC), to be held at 3 PM on Tuesday, June 3, 2003, aboard the Princess Tina, which will be moored at the Bickerdike Terminal, Pier M5 or M6, located at the corner of Bonaventure Expressway and Eipierre DuPuis, Montreal, Quebec. The agenda for this meeting will be as follows: Opening Remarks; Consideration of Minutes of Past Meeting; Review of Programs; New Business; and Closing Remarks.

Attendance at meeting is open to the interested public but limited to the space available. With the approval of the Administrator, members of the public may present oral statements at the meeting. Persons wishing further information should contact, not later than May 30, 2003, Anita K. Blackman, Chief of Staff, Saint Lawrence Seaway Development Corporation, 400 Seventh Street, SW., Washington, DC 20590; 202–366–0091.

Any member of the public may present a written statement to the Advisory Board at any time.

Issued at Washington, DC on May 23, 2003.

Marc C. Owen,

Chief Counsel.

[FR Doc. 03–13415 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–61–P

DEPARTMENT OF THE TREASURY

Treasury Advisory Committee on Commercial Operations of the U.S. Customs Service

AGENCY: Departmental Offices, Treasury.

ACTION: Notice of meeting.

SUMMARY: This notice announces the date, time, and location for the third meeting of the eighth term of the Treasury Advisory Committee on Commercial Operations of the U.S. Customs Service (COAC), and the expected agenda for its consideration.

DATES: The next meeting of the COAC will be held on Friday, June 20, 2003 at 9 a.m. at the U.S. Mint, Conference Rooms A and B (second floor), located at 801 9th Street, NW., Washington, DC. The duration of the meeting will be approximately four hours.

FOR FURTHER INFORMATION CONTACT: Robyn Day at (202) 927–1440.

SUPPLEMENTARY INFORMATION: This meeting is open to the public. However, participation in the COAC's deliberations is limited to COAC members, Homeland Security and Treasury Department staff, and persons invited to attend the meeting for special presentations. All persons entering the building must be cleared by building security at least 72 hours in advance of the meeting. Personal data to obtain this clearance must be submitted to Robyn Day at (202) 927–1440 no later than 2 p.m. EST on June 16, 2003.

Agenda

The COAC is expected to pursue the following agenda, which may be modified prior to the meeting:

(1) Customs and Border Protection Organization under the Department of Homeland Security.

(2) Customs-Trade Partnership Against Terrorism.

(3) Trade Act of 2002.

(4) 24–Hour Manifest Rule.

(5) COAC Administration under DHS and Treasury.

(6) Customs Participation on WCO Task Force for Global Security Standard.

Dated: May 22, 2003.

Timothy E. Skud,

Deputy Assistant Secretary.

[FR Doc. 03–13454 Filed 5–28–03; 8:45 am]

BILLING CODE 4810–25–P

Corrections

Federal Register

Vol. 68, No. 103

Thursday, May 29, 2003

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 52

[FAC 2001–14; Item VIII]

Federal Acquisition Regulation; Technical Amendments

Correction

In rule document 03–12308 appearing on page 28098 in the issue of Thursday, May 22, 2003, make the following correction:

On page 28098, in the second column, under the heading **DATES**, ''June 23, 2003'' should read, ''May 22, 2003''.

[FR Doc. C3–12308 Filed 5–28–03; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Thursday,
May 29, 2003

Part II

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Printing, Coating, and Dyeing of Fabrics and Other Textiles; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[OAR2003–0014—FRL–7461–9]

RIN 2060–AG98

National Emission Standards for Hazardous Air Pollutants: Printing, Coating, and Dyeing of Fabrics and Other Textiles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action promulgates national emission standards for hazardous air pollutants (NESHAP) for existing and new fabric and other textile coating, printing, slashing, dyeing, and finishing operations. The final standards implement section 112(d) of the Clean Air Act (CAA) by requiring all major sources to meet the hazardous air pollutants (HAP) emission standards reflecting the application of the maximum achievable control technology (MACT).

The EPA has estimated that there are approximately 135 major source facilities in the printing, coating, and dyeing of fabrics and other textiles source category. The principal HAP emitted by these sources include toluene, methyl ethyl ketone (MEK), methanol, xylenes, methyl isobutyl ketone (MIBK), methylene chloride, trichloroethylene, n-hexane, glycol ethers (ethylene glycol), and formaldehyde. The final rule will reduce nationwide organic HAP emissions from major sources by approximately 4,100 tons per year or about 60 percent from baseline emissions.

Exposure to these substances has been demonstrated to cause adverse health effects such as irritation of the eye, lung, and mucous membranes, effects on the central nervous system, and damage to the liver. The EPA has classified two of the HAP, methylene chloride and trichloroethylene, as probable or possible human carcinogens. We do not have the type of current detailed data on each of the facilities covered by the final rule and the people living around the facilities that would be necessary to conduct an analysis to determine the actual population exposures to the HAP emitted from these facilities and potential for resultant health effects. Therefore, we do not know the extent to which the adverse health effects described above occur in the populations surrounding these facilities. However, to the extent the adverse effects do occur, the final rule will reduce emissions and subsequent exposures.

DATES: May 29, 2003. The incorporation by reference of certain publications listed in today's final rule is approved by the Director of the Federal Register as of May 29, 2003.

ADDRESSES: *Docket.* Docket ID No. OAR–2003–0014 (formerly Docket No. A–97–51) is located at the EPA Docket Center, EPA West, U.S. EPA (6102T), 1301 Constitution Ave., NW., Room B102, Washington, DC 20460.

Background Information Document. A background information document (BID) for the promulgated NESHAP may be obtained from the docket; the U.S. EPA Library (C267–01), Research Triangle Park, NC 27711, telephone (919) 541–2777; or from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161, telephone (703) 487–4650. Refer to ''National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Category: Printing, Coating, and Dyeing of Fabrics and Other Textiles—Background Information for Promulgated Standards'' (EPA–453/R–03–006). The promulgation BID contains a summary of public comments made on the proposed standards and the EPA responses to the comments.

FOR FURTHER INFORMATION CONTACT: For information concerning applicability and rule determinations, contact your State or local air pollution control agency representative or the appropriate EPA Regional Office Representative. For information concerning the analyses performed in developing the final rule, contact Mr. Paul Almodóvar, Coatings and Consumer Products Group (C539–03), Emission Standards Division, U.S. EPA, Research Triangle Park, NC 27711; telephone number (919) 541–0283; facsimile number (919) 541–5689; electronic mail (e-mail) address: *almodovar.paul@epa.gov.*

SUPPLEMENTARY INFORMATION: *Regulated Entities.* The source category definition includes sources that engage in the coating, printing, slashing, dyeing, or finishing of any fabric or other textile. In general, such sources are covered under the North American Industrial Classification System (NAICS) codes. However, sources classified under other NAICS codes may be subject to the final standards if they meet the applicability criteria. Not all sources classified under the NAICS codes in the following table are subject to the final rule because some of the classifications cover products outside the scope of the NESHAP for printing, coating, and dyeing of fabrics and other textiles.

Categories and entities potentially regulated by this action include:

Category	NAICS code	Examples of regulated entities
Industry	31321	Broadwoven fabric mills.
	31322	Narrow fabric mills and Schiffli machine embroidery.
	313241	Weft knit fabric mills.
	313311	Broadwoven fabric finishing mills.
	313312	Textile and fabric finishing (except broadwoven fabric) mills.
	313320	Fabric coating mills.
	314110	Carpet and rug mills.
	326220	Rubber and plastics hoses and belting and manufacturing.
	339991	Gasket, packing, and sealing device manufacturing.
Federal government		Not affected.
State/local/tribal government		Not affected.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your operation is regulated by this action, you should examine the applicability criteria in § 63.4281 of the final rule. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Docket. The EPA has established an official public docket for this action under Docket ID No. OAR–2003–0014 (formerly Docket No. A–97–51). The official public docket consists of the documents specifically referenced in

this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, EPA West, Room B–102, 1301 Constitution Avenue, NW., Washington, DC 20460. The Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Docket is (202) 566–1742. A reasonable fee may be charged for copying docket materials.

Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/edocket/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified above. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Worldwide Web (WWW). In addition to being available in the docket, an electronic copy of the final rule will also be available on the WWW through EPA's Technology Transfer Network (TTN). Following signature by the EPA Administrator, a copy of the final rule will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541–5384.

Judicial Review. This action constitutes final administrative action on the proposed NESHAP for printing, coating, and dyeing of fabrics and other textiles (67 FR 45054, July 11, 2002). Under CAA section 307(b)(1), judicial review of the final rule is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by July 28, 2003. Only those objections to the final rule which were raised with reasonable specificity during the period for public comment may be raised during judicial review. Under CAA section 307(b)(2), the requirements established by today's final rule may not be challenged later in civil or criminal proceedings brought by EPA to enforce the requirements.

Outline. The information presented in this preamble is organized as follows:

I. Background
A. What Is the Source of Authority for Development of NESHAP?
B. What Criteria Are Used in the Development of NESHAP?
II. What Changes and Clarifications Have we Made to the Proposed Standards?
A. Applicability
B. Overlap With Other Rules
C. Affected Source
D. Emission Limits and Options
E. General Compliance Requirements
F. Requirements for Compliance Options
III. Summary of the Final Rule
A. What Source Categories and Subcategories Are Affected by the Final Rule?
B. What Is the Affected Source?
C. What Are the Emission Limits, Operating Limits, and Other Standards?
D. What Are the Testing and Initial Compliance Requirements?
E. What Are the Continuous Compliance Provisions?
F. What Are the Notification, Recordkeeping, and Reporting Requirements?
IV. Summary of Environmental, Energy, and Economic Impacts
A. What Are the Air Impacts?
B. What Are the Cost Impacts?
C. What Are the Economic Impacts?
D. What Are the Non-Air Health, Environmental, and Energy Impacts?
V. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
G. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks
H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer Advancement Act
J. Congressional Review Act

I. Background

A. What Is the Source of Authority for Development of NESHAP?

Section 112 of the CAA requires us to list categories and subcategories of major sources and area sources of HAP and to establish NESHAP for the listed source categories and subcategories. The Printing, Coating, and Dyeing of Fabrics source category was listed on July 16, 1992 (57 FR 31576) under the Surface Coating Processes industry group. We proposed standards for and revised the title of this source category to Printing, Coating, and Dyeing of Fabrics and Other Textiles on July 11, 2002 (67 FR 45054). The title was revised to clarify the applicability of the standards to organic HAP-emitting operations performed on textile substrates including, but not limited to, fabric.

A major source of HAP is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year (tpy) or more of any one HAP or 25 tpy of any combination of HAP. An area source is any stationary source of HAP that is not a major source.

B. What Criteria Are Used in the Development of NESHAP?

Section 112 of the CAA requires that we establish NESHAP for the control of HAP from both new and existing major sources. The CAA requires the NESHAP to reflect the maximum degree of reduction in emissions of HAP that is achievable. This level of control is commonly referred to as the MACT, for maximum achievable control technology.

The MACT floor is the minimum control level allowed for NESHAP and is defined under section 112(d)(3) of the CAA. In essence, the MACT floor ensures that the standard is set at a level that assures that all major sources achieve the level of control already achieved by the better-controlled and lower-emitting sources in each source category or subcategory. For new sources, the MACT standards cannot be less stringent than the emission control that is achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than standards for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources).

In developing MACT, we also consider control options that are more stringent than the floor. We may establish standards more stringent than the floor based on the consideration of the cost of achieving the emissions reductions, any non-air health and environmental impacts, and energy requirements.

II. What Changes and Clarifications Have We Made to the Proposed Standards?

In response to public comments received on the proposed standards, we made several changes in developing the final rule. The substantive comments and our responses and rule changes are summarized in the following sections. A more detailed summary of comments and responses can be found in the BID for the final rule which is available from several sources (see **ADDRESSES**).

A. Applicability

We have made several changes to clarify the applicability of the final rule to certain coating, printing, slashing, dyeing, and finishing operations. We have also made changes to clarify which other web surface coating operations are not subject to the requirements of this final rule.

One commenter requested that we clarify the intent of proposed exemptions for research and development facilities from the rule requirements. The commenter believes the word facility and the definition of research or laboratory facility could be read to mean that the research or laboratory facility must be a facility separate from any facility that is doing commercial coating, dyeing, etc., in order to be exempt from subpart OOOO applicability. Typically in this source category, research and development activities are conducted on web coating and printing lines or dyeing and finishing operations located within a manufacturing plant. These research and development operations are co-located with manufacturing lines in order to test the product at the same manufacturing variables (*e.g.*, temperature and humidity) as those of the products currently being used. Therefore, the final rule language has been written to reflect this. The use of the terms research or laboratory operations, rather than facilities, will also make this language consistent with the affected source description in the final rule. A corresponding change has also been made to the definition of research or laboratory facility to reflect this change.

One commenter observed that the proposal preamble described exemptions to the proposed rule for certain tape and tire manufacturing activities covered by the NESHAP for Paper and Other Web Coating and the NESHAP for Tire Manufacturing MACT, respectively. The commenter pointed out that the proposed rule text failed to mention any of these exemptions. These explicit exemptions were inadvertently omitted from the proposed rule language. The final rule has been written to include the appropriate exemptions.

Three commenters expressed concern that, as proposed, the final rule could be interpreted to apply to synthetic fiber manufacturing operations. We have written the final rule to clarify that coating, slashing, dyeing, and finishing operations that are part of a synthetic fiber manufacturing process, and are part of the affected source of another NESHAP, such as the Group IV Polymers and Resins NESHAP (40 CFR 63, subpart JJJ) are not subject to the requirements of the final rule. For example, finishes that are applied in an affected source to which subpart JJJ applies are not subject to the requirements of the final rule.

One commenter noted the preamble to the proposed rule stated that coating and printing operations conducted at ambient temperatures and not involving drying or curing equipment are not subject to the provisions of the rule. The commenter requested that this language be included in the applicability section of the final regulation. In order to clarify the applicability of the final rule to web coating and printing operations conducted at ambient temperatures, the final rule has been written to exclude web coating or printing operations that do not involve drying or curing equipment such as ovens, tenter frames, steam cans, or dryers from the requirements of the final rule. Web coating and printing operations that dry at ambient temperatures are not representative of the coating and printing operations in the database used to determine the MACT floor for the coating and printing subcategory. These low-production rate operations make up only a small segment of the overall coating and printing industry. It was also determined that the emission capture and control technologies applicable to these operations would be considerably different (because of temperature, concentration, and flow rate differences) than those operations involving drying and curing equipment which are the basis of the MACT floor determination.

B. Overlap With Other Rules

Two commenters pointed out that the preamble text of the proposed rule created duplicate applicability for some sources, *i.e.*, web coating lines that coat paper and other web substrates as well as fabric and other textile substrates. The commenters requested clarification on which NESHAP would apply to web coating lines that coat both types of substrate. The Paper and Other Web Coating NESHAP applies to web coating lines engaged in the coating of fabric for use in flexible packaging, pressure sensitive tapes and abrasive materials. The final rule has been written to clarify that web coating lines where both fabric and other webs are coated for use in flexible packaging, pressure sensitive tapes or abrasive materials or where fabric is being laminated to a paper and other web substrate are subject to 40 CFR 63, subpart JJJJ, and not today's final rule.

For other web coating lines engaged in the coating of fabric and other webs on the same web coating line, we have written in a provision to the final rule whereby a source can determine which MACT standard they must comply with based on the predominant surface coating activity conducted on the web coating line. Predominant activity has been determined to be 90 percent or more of the mass of substrate coated. For example, a web coating line that coats 90 percent paper and 10 percent fabric substrates would have to comply with the Paper and Other Web NESHAP (40 CFR 63, subpart JJJJ).

C. Affected Source

Seven commenters stated that the proposed rule was inconsistent with regard to its applicability to cleaning materials and preparation activities. The commenters requested revisions to the proposed rule related to its applicability to cleaning materials and preparation activities. We agree with the commenters that the final rule should not regulate cleaning materials and preparation materials in the slashing or the dyeing and finishing subcategories. Slashing and dyeing and finishing operations are aqueous processes, and, therefore, the cleaning materials and preparation activities used in these operations do not contain organic HAP. The most common cleaning material used in these operations is water. The final rule has been written to clarify that cleaning and preparation materials used in the slashing and the dyeing and finishing subcategories are not regulated materials.

D. Emission Limits and Options

Seven commenters requested that an add-on control compliance option be included in the final rule for the dyeing and finishing subcategory. The commenters pointed out that as the industry moves from mass base goods production to specialized niche production, and as new products and technologies are developed and implemented, flexibility in the production process will be the key to the survival of this industry. We agree

with the commenters, and, therefore, in order to provide more compliance flexibility with the emission limits, the final rule has been written to include an emission rate with add-on control device compliance option for the dyeing and finishing subcategory.

Numerous comments were received concerning high molecular weight, high boiling point, and highly water-soluble organic HAP from dyeing and finishing sources that are not emitted in the dyeing and finishing process but are discharged to the wastewater. This class of organic HAP has a low emission potential (*i.e.*, low Henry's Law constant) and also are typically readily biodegraded; as a result they are not emitted to the atmosphere in wastewater collection and treatment operations. The commenters requested that the final rule should allow sources to take into account in their compliance demonstrations organic HAP that are discharged to the wastewater and not emitted to the atmosphere. The final rule has been written to allow a dyeing and finishing affected source to account for organic HAP that are discharged to wastewater. An equivalent emission rate compliance option has been written in the final rule, and a procedure has been added to account for the mass of organic HAP contained in wastewater discharged to a publically owned treatment works (POTW) or onsite secondary wastewater treatment.

In order to be able to use the equivalent emission rate compliance option, a source must make an initial compliance demonstration that at least 90 percent of the mass of organic HAP contained in dyeing and finishing materials applied in the affected source is discharged to the wastewater; and that the total organic HAP emissions from the dyeing and finishing affected source are less than 10 tpy. The source must also document that the affected wastewater streams are discharged to a POTW or treated onsite in a treatment system that includes at least secondary treatment with biological treatment processes.

E. Requirements for Compliance Options

Several commenters asserted that the proposed rule did not include a compliance option for the web coating and printing subcategory which takes into account processes that use reactive materials that are not emitted to the atmosphere. The final rule has been written to allow the use of EPA Method 24 of 40 CFR part 60 Appendix A, for multi-component coatings with reactive materials to determine the mass fraction of non-aqueous volatile matter. This empirical value can be used as a substitute for the mass fraction of organic HAP calculated from the sum of organic HAP in each coating component. Also, you may submit an alternative technique for approval by the Administrator, *e.g.*, stack testing with an enclosure to quantify the organic HAP actually emitted from the web coating process.

Several commenters requested that the compliance period for affected sources using the emission rate compliance option be changed to a 12-month rolling average period. Four of the commenters also submitted plant specific data demonstrating the extreme variability within both the coating and printing and the dyeing and finishing subcategories over time. The commenters asserted that a 12-month rolling average would take into account the seasonal variations in this industry and would better reflect the data used to set the MACT floor. Upon review of the data submitted by the commenters, the final rule has been written to allow a 12-month rolling average compliance period for sources using the emission rate compliance option. This would allow for the month-to-month variability in organic HAP content of coating, dyeing, and finishing materials.

Several commenters stated that the proposed rule was unclear as to how the compliance averaging calculations for dyeing materials are to be performed. The final rule language has been written to clarify that these compliance averaging calculations for dyeing materials should include only regulated materials as received from the manufacturer or supplier, and prior to any on-site alteration of the material (*e.g.*, mixing with solvent); and, that water added in a mixing operation is not a regulated material and should not be included in the determination of the total mass of dyeing and finishing materials applied during the compliance period. This would be consistent with how the MACT floors for this subcategory were calculated.

III. Summary of the Final Rule

A. What Source Categories and Subcategories Are Affected by the Final Rule?

The final rule applies to you if you own or operate a fabric or other textile coating, printing, slashing, dyeing, or finishing operation or group of such operations that is a major source, or is located at a major source, or is part of a major source of HAP emissions, whether or not you manufacture the substrate. The coating, printing, slashing, dyeing, or finishing operations themselves are not required to be major sources of HAP emissions in order for them to be covered by the final rule. As long as some part of the facility where the operations are located (*e.g.*, a process boiler or manufacturing operation associated with production of the final product) causes it to be a major source, the coating, printing, slashing, dyeing, and finishing operations are subject to the standards.

Any major HAP-emitting facility that performs coating, printing, slashing, dyeing, or finishing of fabric or other textiles is in this source category. As defined in the final rule, fabric or other textiles includes, but is not limited to, yarn, fiber, cord, thread, fabric and textile products, tents, roofing, soft baggage, marine fabric, drapery linings, flexible hoses, hot-air balloons, and awnings. The source category includes three subcategories (web coating and printing, slashing, and dyeing and finishing) as described in the following paragraphs.

The web coating and printing subcategory encompasses coating activities and equipment used to apply semi-liquid coating material to one or both sides of a textile web substrate. Once the coating is dried (and cured, if necessary) it bonds with the substrate to form a continuous solid film for decorative, protective, or functional purposes. Similarly, the web coating and printing subcategory includes printing activities and equipment used to apply color and patterns to textile substrates, usually in the form of a paste. After application of the printing material, the substrate is treated with steam, heat, or chemicals to fix the color.

The slashing subcategory includes the yarn preparation process performed on warp yarn prior to weaving. Slashing is the application of a chemical solution (known as sizing) to a yarn in a water solution followed by squeezing (dewatering) and drying.

The dyeing and finishing subcategory includes the equipment and operations involved in two separate but related processes that are both performed at some sources, while only one or the other is performed at other sources. Dyes and finishes are applied to yarn, fiber, cord, thread, or fabric in aqueous solutions and then dried. Dyeing is the application of color to the whole body of a textile substrate. Finishing is a process performed after dyeing that improves the appearance and/or usefulness of a textile substrate.

You are not subject to the final rule if your coating, printing, slashing, dyeing, or finishing operation is located at an area source. An area source of HAP

is any facility that has the potential to emit HAP but is not a major source. You may establish area source status by limiting the source's potential to emit HAP through appropriate mechanisms available through your permitting authority.

Exclusions from the source category include coating, printing, slashing, dyeing or finishing at a source using only coating, printing, slashing, dyeing, finishing, thinning, and cleaning materials that contain no organic HAP as defined in the final rule; coating, printing, slashing, dyeing, or finishing that occurs in a research or laboratory operation or that is part of a janitorial, building, and facility maintenance operation; coating, printing, slashing, dyeing, or finishing used by a facility and not for commerce, unless organic HAP emissions from these operations equal or exceed the facility major source HAP emissions threshold; a web coating line that applies coatings to both paper and fabric and other textile substrates used in flexible packaging, pressure sensitive tape or abrasive materials or where fabric is being laminated to a paper; a web coating line that applies coatings to tire cord and that also sometimes applies coatings to textile cord used in the production of belts and hoses; a coating, slashing, dyeing, or finishing operation that is conducted during a synthetic fiber manufacturing process included in the affected source of a NESHAP under 40 CFR 63; and a web coating or printing operation conducted at ambient temperatures and that does not involve drying or curing equipment such as, ovens, tenter frames, steam cans, or dryers; and coating, printing, slashing, dyeing, or finishing operations performed on-site at installations owned or operated by the Armed Forces of the United States (including the Coast Guard and the National Guard of any State).

Web coating lines engaged in the coating of fabric and other webs on the same web coating line, must comply with the NESHAP applicable to the web coating line based on predominant surface coating activity conducted on the web coating line. Predominant activity has been determined to be 90 percent or more of the mass of substrate coated. For example, a web coating line that coats 90 percent paper and 10 percent fabric substrates would have to comply with the Paper and Other Web NESHAP (40 CFR 63, subpart JJJJ).

B. What Is the Affected Source?

An affected source is a stationary source, a group of stationary sources, or part of a stationary source to which a specific emission standard applies. The final rule defines the affected source for each subcategory respectively, as the collection of all equipment associated with the web coating and printing, the slashing, or the dyeing and finishing performed on a textile substrate. For the purpose of defining the affected source, the textile substrate includes staple fibers and filaments suitable for conversion to or use as yarns, or for the preparation of woven, knit, or nonwoven fabrics; yarns made from natural or manufactured fibers; fabrics and other manufactured products made from staple fibers and filaments and from yarn; and garments and other articles fabricated from fibers, yarns, or fabrics. Also for each subcategory, the specific regulated materials are defined. Regulated materials are the organic HAP-containing materials that are the source of organic HAP emissions limited by the requirements of the NESHAP.

The affected source for the web coating and printing subcategory includes: All web coating and printing equipment used to apply cleaning materials to a substrate on the coating or printing line to prepare it for coating or printing material application, to apply coating or printing materials to a substrate and to dry or cure the coating or printing materials after application by exposure to heat or radiation (coating or printing material drying or curing); equipment used to clean web coating/printing operation equipment; all containers used for storage and vessels used for mixing coating, printing, thinning, or cleaning materials; all equipment and containers used for conveying coating, printing, thinning, or cleaning materials; all containers used for storage and all equipment and containers used for conveying waste materials generated by a web coating or printing operation; and all equipment, structures, and devices used to convey, treat, or dispose of wastewater streams or residuals generated by a web coating or printing operation. The regulated materials for the coating and printing subcategory are the coating, printing, thinning and cleaning materials used in the affected source.

The affected source for the slashing subcategory includes: All slashing equipment used to apply and dry size on warp yarn; all containers used for storage and vessels used for mixing slashing materials; all equipment and containers used for conveying slashing materials; all containers used for storage and all equipment and containers used for conveying waste materials generated by a slashing operation; and all equipment, structures, and devices used to convey, treat, or dispose of wastewater streams or residuals generated by a slashing operation. The regulated materials for the slashing subcategory are the slashing materials used in the affected source.

The affected source for the dyeing and finishing subcategory includes: All dyeing and finishing equipment used to apply dyeing or finishing materials, to fix dyeing materials to the substrate, to rinse the textile substrate, or to dry or cure the dyeing or finishing materials; all containers used for storage and vessels used for mixing dyeing or finishing materials; all equipment and containers used for conveying dyeing or finishing materials; all containers used for storage and all equipment and containers used for conveying waste materials generated by a dyeing or finishing operation; and all equipment, structures, and devices used to convey, treat, or dispose of wastewater streams or residuals generated by a dyeing or finishing operation. The regulated materials for the dyeing and finishing subcategory are the dyeing and finishing materials used in the affected source.

C. What Are the Emission Limits, Operating Limits, and Other Standards?

Today's final rule limits organic HAP emissions from coating, printing, slashing, dyeing, and finishing operations. The final rule includes emission limits, operating limits, and work practice standards. Emission limits are established for the web coating and printing, slashing, and dyeing and finishing subcategories. Operating limits and work practice standards are established for the web coating and printing, and the dyeing and finishing subcategories.

1. *Emission Limits.* In the web coating and printing subcategory, today's final rule provides you the option of limiting organic HAP emissions to the atmosphere from each new and reconstructed affected source to one of the following three specified levels: (1) At least a 98 percent organic HAP overall control efficiency (OCE limit); (2) no more than 0.08 kilograms (kg) organic HAP/kg of coating solids applied (0.08 pound (lb) organic HAP/lb of coating solids applied) during each 12-month compliance period (emission rate limit); or (3) if you are using an oxidizer to control organic HAP emissions, operate the oxidizer such that an outlet organic HAP concentration of no greater than 20 parts per million by volume (ppmv) on a dry basis is achieved and maintain the efficiency of the capture system at 100 percent (outlet concentration limit). The organic HAP emission limits for each existing affected source in the web

coating and printing subcategory are: (1) To achieve at least a 97 percent OCE limit; (2) an emission rate limit of no more than 0.12 kg organic HAP/kg of coating solids applied (0.12 lb organic HAP/lb of coating solids applied) in each 12-month compliance period; or (3) if you are using an oxidizer to control organic HAP emissions, operate the oxidizer to achieve the outlet concentration limit of no greater than 20 ppmv on a dry basis and maintain the efficiency of the capture system at 100 percent.

You may choose from several compliance options in the final rule to achieve the web coating and printing emission limits. You can comply through a pollution prevention approach by applying regulated materials that meet the emission rate limits, either individually (compliant material option) or collectively (emission rate without add-on controls option), during each compliance period. Second, you can use a capture system and add-on control device to meet either the applicable organic HAP OCE limit or emission rate limit. Third, you can use a 100 percent efficient capture system and an oxidizer that reduces organic HAP emissions to no more than 20 ppmv.

In the slashing subcategory, we are requiring each new, reconstructed and existing affected source to emit no organic HAP. This is not an absolute zero organic HAP limit since the compliance procedures specify that to determine organic HAP emissions, you count only organic HAP present in the materials you use at 0.1 percent by mass or more for Occupational Safety and Health Administration (OSHA)-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and at 1 percent or more for other organic HAP compounds. To comply with the slashing organic HAP emission limits, you must apply only materials that individually meet the standard during each compliance period.

In the dyeing and finishing subcategory, we are limiting organic HAP emissions from each new, reconstructed and existing affected source that conducts dyeing operations only or both dyeing and finishing operations to no more than 0.016 kg organic HAP per kg of dyeing material used (0.016 lb organic HAP per lb of dyeing material used) for each 12-month compliance period. You can comply with the dyeing and finishing organic HAP emission rate by applying materials that meet the emission rate, either individually or collectively, during each 12-month compliance period. Each new, reconstructed and existing affected source that conducts only finishing operations is required to emit no more than 0.0003 kg of organic HAP per kg of finishing materials.

We are also including an equivalent emission rate option in the dyeing and finishing subcategory. In order to be able to use the equivalent emission rate compliance option, you must demonstrate that at least 90 percent of the mass of organic HAP contained in dyeing and finishing materials applied in the dyeing and finishing affected source are discharged to a wastewater treatment system and not emitted to the atmosphere; and that the total organic HAP emissions from the dyeing and finishing affected source must be less than 10 tons per year. To demonstrate continuous compliance you must document that your dyeing/finishing affected source operates within the operating scenarios used to demonstrate initial compliance and that affected wastewater streams are discharged to a POTW or treated onsite in a wastewater treatment system with biological treatment. You also must maintain purchase records showing that organic HAP emissions do not exceed 10 tons for each 12-month compliance period.

2. *Operating Limits.* If you reduce emissions from web coating and printing or dyeing and finishing operations by using a capture system and add-on control device (other than a solvent recovery system for which you conduct a liquid-liquid material balance), the operating limits apply to you. These limits are site-specific parameter limits that you determine during the initial performance test of the emission control system. For capture systems, you must develop a capture system monitoring plan. The monitoring plan must identify the operating parameter to be monitored, explain why this parameter is appropriate for demonstrating ongoing compliance, and identify the specific monitoring procedures. In the plan, you must specify operating limits for the capture system operating parameter that demonstrate compliance with the applicable emission standard in the final rule. The monitoring plan must be available for inspection by your permitting authority upon request.

For thermal oxidizers, you must monitor the temperature in the firebox. For catalytic oxidizers, you either monitor the temperature at the inlet to the catalyst bed and the temperature difference across the catalyst bed, or you monitor the temperature at the inlet to the catalyst bed and prepare and implement an inspection and maintenance plan that includes periodic catalyst activity checks. For a control device other than an oxidizer or if you wish to monitor an alternative parameter and comply with a different operating limit, you must apply to the Administrator for approval of an alternative monitoring method.

The site-specific parameter limits that you establish must reflect operation of the capture system and add-on control devices during a performance test that demonstrates achievement of the emission limits during representative operating conditions.

3. *Work Practice Standards.* If you use an emission capture system and add-on control device for compliance, you are required to develop and implement a work practice plan to minimize organic HAP emissions from mixing operations, storage tanks and other containers, and handling operations for regulated materials and waste materials.

4. *Operations During Startup, Shutdown, or Malfunction.* If you use a capture system and add-on control device for compliance, you are required to develop and operate according to a startup, shutdown, and malfunction plan (SSMP) during periods of startup, shutdown, or malfunction of the capture system and add-on control device.

5. *General Provisions.* The General Provisions (40 CFR part 63, subpart A) also apply to you as indicated in the final rule. The General Provisions codify certain procedures and criteria for all 40 CFR part 63 NESHAP. The General Provisions contain administrative procedures, preconstruction review procedures for new sources, and procedures for conducting compliance-related activities such as notifications, reporting and recordkeeping, performance testing, and monitoring. The final rule refers to individual sections of the General Provisions to emphasize key sections that are relevant. However, unless specifically overridden in the final rule, all of the applicable General Provisions requirements apply to you.

D. What Are the Testing and Initial Compliance Requirements?

1. *Compliance Dates.* Existing affected sources will have to be in compliance with today's final rule no later than May 30, 2006. New and reconstructed affected sources will have to be in compliance upon startup of the affected source or by May 29, 2003, whichever is later.

Except for affected sources required to conduct performance tests, the initial compliance period for the compliant material option or the organic HAP overall control efficiency and oxidizer outlet organic HAP concentration options begins on the compliance date

and ends on the last day of the first full month following the compliance date. For affected sources required to conduct performance tests, the initial compliance period ends on the last day of the first full month following the performance test if the performance test is conducted later than the compliance date (the final rule allows the test to be conducted up to 180 days later).

Except for affected sources required to conduct performance tests, the initial compliance period for the emission rate without add-on controls option and the emission rate with add-on controls option begins on the compliance date and ends on the last day of the 12th full month following the compliance date. For affected sources required to conduct performance tests, the initial compliance period ends on the last day of the 12th full month following the performance test if the performance test is conducted later than the compliance date (the final rule allows the test to be conducted up to 180 days later).

Being in compliance means that the owner or operator of the affected source meets the requirements to achieve the emission limitations during the initial compliance period. At the end of the initial compliance period, the owner or operator will use the data and records generated to determine whether or not the affected source is in compliance with the organic HAP emission limit and other applicable requirements for that period. If the affected source does not meet the emission limit and other applicable requirements, it is out of compliance for the entire initial compliance period.

2. *Emission Limits.* With the exception of the slashing emission limit, there are several options for complying with the various emission limits specified in today's rule; the testing and initial compliance requirements vary accordingly. You will be able to use different compliance options for different coating, printing, dyeing, and finishing operations in the affected source for each subcategory and also for the same operation at different times, with the exception of the equivalent emission rate option for the dyeing and finishing affected source. If you choose to apply the equivalent emission rate option to your dyeing and finishing operations, it must be applied to the entire dyeing and finishing affected source.

3. *Compliance Based on Materials Applied in the Affected Source.* If you demonstrate compliance with the web coating and printing emission limits based on the materials applied, you must determine the mass of organic HAP and the mass fraction of solids in all materials applied during the initial compliance period. You are required to demonstrate either that the organic HAP content of each coating and printing material meets the applicable emission limit and that you apply no organic HAP-containing thinning or cleaning materials (compliant material option); or that the total mass of organic HAP in all coating, printing, thinning, and cleaning materials applied divided by the total mass of solids in coating and printing materials applied meets the applicable emission limit (emission rate without add-on controls option).

The compliant material option is a pollution prevention option that allows you to easily demonstrate compliance by applying only low-organic HAP or non-organic HAP coating and printing materials. If you apply coating and printing materials that, based on their organic HAP content, individually meet the kg (lb) organic HAP emitted per kg (lb) solids applied levels in the applicable emission limits of the final rule and you apply only non-organic HAP thinners and other additives and cleaning materials, this compliance option is available to you. For this option, we have minimized recordkeeping and reporting requirements. You demonstrate compliance by using readily available purchase records containing manufacturer's formulation data to determine the organic HAP content of each coating, printing, or other material and the amount of each material applied. You do not need to perform any detailed emission rate calculations.

To demonstrate compliance with the compliant material option, you must demonstrate that the organic HAP content of each coating and printing material applied meets the applicable emission limit in the final rule, and that you applied no organic HAP-containing thinning or cleaning materials. For example, if you are using the compliant materials option for your existing source, you must demonstrate that: (1) Each coating and printing material applied has an organic HAP content no greater than 0.12 kg (0.12 lb) organic HAP per kg (lb) solids applied, (2) and that you applied no organic HAP-containing thinning or cleaning materials. Note that no organic HAP is not intended to mean a zero concentration. Materials that contain no organic HAP as defined in the final rule mean materials that contain organic HAP levels below typical reporting levels. These typical reporting levels only count organic HAP that are present at 0.1 percent or more by mass for OSHA-defined carcinogens and at 1.0 percent or more by mass for other compounds.

To determine the mass fraction of organic HAP in coating, printing, thinning, and cleaning materials and the mass fraction of solids in coating and printing materials, you may rely on manufacturer's formulation data. You are not required to perform tests or analysis of the material if formulation data are available. Alternatively, you can use results from the test methods listed below. You may also use alternative test methods provided you get EPA approval in accordance with 40 CFR 63.7(f). However, if there is any inconsistency between the test method results (either EPA's or an approved alternative) and manufacturer's data, the test method results would prevail for compliance and enforcement purposes.

- For mass fraction of organic HAP, you use EPA Method 311 of 40 CFR part 63, appendix A;
- The final rule allows you to use nonaqueous volatile matter as a surrogate for organic HAP, which would include all organic HAP plus all other organic compounds, and excluding water. If you choose this option, you use EPA Method 24 of 40 CFR part 60, appendix A; and
- For mass fraction of solids, you use EPA Method 24 of 40 CFR part 60, appendix A.

For multi-component coatings with reactive materials, the final rule allows the use of EPA Method 24 on the coating as applied to determine the mass fraction of non-aqueous volatile matter. You may use that value as a substitute for the mass fraction of organic HAP determined from the sum of organic HAP in each coating component. Also, you may submit an alternative technique for approval by the Administrator, (*e.g.*, stack testing with an enclosure) to quantify the organic HAP actually emitted from the coating process.

The emission rate without add-on controls option is a pollution prevention option where you can demonstrate compliance based on the organic HAP contained in the mix of coating, printing, thinning, and cleaning materials you apply. This option allows you the flexibility to apply some individual coating or printing materials that do not individually meet the emission limit if you apply other low-organic HAP or non-organic HAP coating or printing materials such that overall emissions from the affected source during the compliance period meet the emission limit.

To demonstrate initial compliance with the emission rate limit without

add-on controls option, you are required to:

- Determine the quantity of each coating, printing, thinning, and cleaning material you applied.
- Calculate the mass of organic HAP in each coating, printing, thinning, and cleaning material you applied using the same types of data and methods previously described for the compliant material option.
- Determine the mass fraction of solids for each coating and printing material you applied using the same types of data or methods described for the compliant material option.
- Calculate the total mass of organic HAP in all regulated materials applied and total mass of solids for all coating and printing materials applied. You may subtract from the total mass of organic HAP the amount contained in waste materials you send to a hazardous waste treatment, storage, and disposal facility regulated under 40 CFR part 262, 264, 265, or 266.
- Calculate the ratio of the total mass of organic HAP to the total mass of solids for the regulated materials applied.
- Record the calculations and results and include them in your Notification of Compliance Status.

Note that if you choose to use this option for a particular web coating/printing operation or group of operations rather than for an entire affected source, you must calculate the organic HAP emission rate using just the materials applied in that operation or group. You are required to separately demonstrate compliance for all other operations in the affected source.

To demonstrate compliance with the slashing emission limits, you must use the compliant material option and demonstrate that each slashing material applied during the initial compliance period contains no organic HAP. As was noted regarding thinning or cleaning materials applied in web coating/printing operations, no organic HAP is not intended to mean a zero concentration. Materials that contain no organic HAP should be interpreted to mean materials that contain organic HAP levels below the levels defined in the final rule, which (as previously noted) are typical reporting levels.

To demonstrate compliance with the dyeing and finishing emission limits, you are required to demonstrate either that the organic HAP content of each dyeing and finishing material applied meets the applicable emission limit (compliant material option), or that the total mass of organic HAP in all dyeing and finishing materials applied divided by the total mass of dyeing and finishing materials applied meets the applicable emission limit (emission rate without add-on controls option).

As previously described for web coating/printing operations, the compliant material option is a pollution prevention option that allows you to easily demonstrate compliance by applying only low-organic HAP or non-organic HAP dyeing and finishing materials. To demonstrate compliance with the compliant material option, you must demonstrate that the organic HAP content of each dyeing and finishing material applied meets the applicable emission limit in the final rule. To determine the mass of organic HAP in dyeing and finishing materials, you must rely on manufacturer's formulation data. You are not required to perform tests or analysis of the material.

Again as previously described for web coating/printing operations, the emission rate without add-on controls option is a pollution prevention option where you can demonstrate compliance based on the organic HAP contained in the mix of dyeing and finishing materials you apply. This option allows you more flexibility than the compliant material option, but requires the calculation of the emission rate each month, for that month and the preceding 11 months. To demonstrate initial compliance with the emission rate without add-on controls option, you are required to:

- Determine the mass of each dyeing and finishing material you applied.
- Calculate the mass of organic HAP in each dyeing and finishing material you applied.
- Calculate the total mass of organic HAP in all regulated materials and the total mass of all regulated materials applied for the compliance period. You may subtract from the total mass of organic HAP the amount contained in waste materials you send to a hazardous waste treatment, storage, and disposal facility regulated under 40 CFR part 262, 264, 265, or 266. You also may subtract from the total mass of organic HAP the amount demonstrated to be discharged to wastewater treatment and not emitted to the atmosphere, in accordance with the final rule requirements.
- Calculate the ratio of the total mass of organic HAP in the regulated materials applied to the total mass of regulated materials applied.
- Record the calculations and results and include them in your Notification of Compliance Status.

Note that if you choose to use this option for a particular dyeing/finishing operation or group of operations rather than for an entire affected source, you would calculate the organic HAP emission rate using just the affected materials applied in that operation or group. You would need to separately demonstrate compliance for all other operations in the affected source.

You may also choose to use the equivalent emission rate option for your dyeing/finishing affected source. If you choose to use the equivalent emission rate option, it must be applied to the entire affected source; you may not use any other compliance option provided for any dyeing/finishing operation in your dyeing/finishing affected source.

In order to be able to use the equivalent emission rate option, you must demonstrate that at least 90 percent of the mass of organic HAP contained in dyeing and finishing materials applied in the dyeing/finishing affected source are discharged to the wastewater treatment system and not emitted to the atmosphere; and the total organic HAP emissions from the dyeing/finishing affected source must be less than 10 tons per year.

To demonstrate initial compliance with the equivalent emission rate option, you are required to:

- Determine the average organic HAP concentration of each affected wastewater stream using EPA Methods 305, 624, 625, 1624, 1625; other EPA methods; or methods other than EPA methods in accordance with specified requirements. You must consider the actual or anticipated production over the compliance period and include all wastewater streams generated by the affected dyeing/finishing operation(s) during this period. A performance test must be performed to characterize the wastewater stream generated for each operating scenario (in terms of factors affecting the fraction of organic HAP discharged to the wastewater, such as the type of substrate, the type and mass fraction of organic HAP entering the dyeing/finishing operation, and the process temperature and pressure) during the compliance period.
- Determine the mass flow rate of each wastewater stream using knowledge of the wastewater, historical records, or measurement.
- Document the wastewater is either discharged to a POTW or treated onsite in a treatment system that includes at least secondary treatment with biological treatment processes.
- Determine the mass of organic HAP contained in all of the wastewater streams characterized by the performance testing.
- Determine the fraction of organic HAP applied in the dyeing/finishing affected source that is discharged to the

wastewater. At least 90 percent of the organic HAP applied must be discharged to the wastewater.

• Determine the organic HAP emissions from the dyeing/finishing affected source. Organic HAP emissions must be less than 10 tons per year.

• Record the calculations and results and include them in your Notification of Compliance Status.

4. *Compliance Based on Using a Capture System and Add-on Control Device.* If you use a capture system and add-on control device on a web coating/printing operation, other than a solvent recovery system for which you conduct a liquid-liquid material balance, you must determine the capture and control efficiencies of the equipment or the oxidizer outlet organic HAP concentration. For the organic HAP emission rate limit, you also must determine the mass fraction of organic HAP and the mass fraction of solids in all materials applied during the initial compliance period. You are required to demonstrate either that the organic HAP OCE is greater than or equal to the applicable organic HAP OCE limit, that the oxidizer outlet organic HAP concentration is no greater than 20 ppmv on a dry basis and the efficiency of the capture system is 100 percent, or that the capture and control system reduces organic HAP emissions to a level no greater than the applicable emission rate limit in the final rule.

If you use a solvent recovery system for which you conduct a liquid-liquid material balance, you are required to demonstrate either that the organic HAP OCE determined by material balance during the initial compliance period is greater than or equal to the applicable organic HAP OCE limit or that the solvent recovery system reduces organic HAP emissions to a level no greater than the applicable emission rate limit.

The testing and initial compliance requirements associated with determining the OCE of the capture system and add-on control device are summarized in the following paragraphs.

If you use a capture system and add-on control device, other than a solvent recovery system for which you conduct material balances, you are required to conduct an initial performance test to determine the capture and control efficiencies of the equipment (or the capture efficiency of the capture system and the oxidizer outlet organic HAP concentration) and to establish operating limits to be achieved on a continuous basis. The performance test must be completed no later than 180 days after the compliance date for affected sources. If you are demonstrating compliance with the applicable emission rate limit with add-on controls, you must schedule the performance test in time to obtain the results for use in calculating your emission rate for the initial compliance period.

You must determine both the efficiency of the capture system and either the organic HAP emission reduction efficiency of the add-on control device or the outlet organic HAP concentration of the oxidizer. To determine the capture efficiency, you must either verify the presence of a permanent total enclosure (PTE) using EPA Method 204 of 40 CFR part 51, appendix M (and all materials must be applied and dried or cured within the enclosure); or use one of three protocols in the final rule to measure capture efficiency. If you have a PTE and all regulated materials are applied and dried or cured within the enclosure and you route all exhaust gases from the enclosure to an add-on control device, then you assume 100 percent capture. To demonstrate compliance with the oxidizer outlet organic HAP concentration limit, 100 percent capture is required.

To determine the organic HAP emission reduction efficiency of the add-on control device, you must conduct measurements of the inlet and outlet gas streams. Only the outlet gas stream must be measured to determine outlet organic HAP concentration. The performance test must consist of three runs, each run lasting 1 hour, using the following EPA Methods in 40 CFR part 60, appendix A:

• Method 1 or 1A for selection of the sampling sites.

• Method 2, 2A, 2C, 2D, 2F, or 2G to determine the gas volumetric flow rate.

• Method 3, 3A, or 3B for gas analysis to determine dry molecular weight. You may also use as an alternative to Method 3B, the manual method for measuring the oxygen, carbon dioxide, and carbon monoxide content of exhaust gas in ANSI/ASME PTC 19.10–1981.

• Method 4 to determine stack moisture.

• Method 25 or 25A to determine organic volatile matter concentration. You must use Method 25A to demonstrate compliance with the oxidizer outlet organic HAP concentration limit because the limit is less than 50 ppmw. Alternatively, any other test method or data that have been validated according to the applicable procedures in Method 301 of 40 CFR part 63, appendix A, and approved by the Administrator, could be used.

If you use a solvent recovery system, you may determine the OCE using a liquid-liquid material balance instead of conducting an initial performance test. If you use the material balance alternative, you are required to measure the amount of all regulated materials applied during the initial compliance period and determine the total volatile matter contained in these materials. You must also measure the amount of volatile matter recovered by the solvent recovery system during the compliance period. Then you must compare the amount recovered to the amount used to determine the OCE. You must record the calculations and results and include them in your Notification of Compliance Status.

Additional testing and initial compliance requirements associated with demonstrating compliance using the emission rate with add-on controls option are as follows:

• Determine the mass fraction of organic HAP in each coating, printing, thinning, and cleaning material applied and the mass fraction of solids in coating and printing materials applied during the initial compliance period, as described previously.

• Calculate the total mass of organic HAP in all regulated materials and total mass of solids for all coating and printing materials. You may subtract from the total mass of organic HAP the amount contained in waste materials you send to a hazardous waste treatment, storage, and disposal facility regulated under 40 CFR part 262, 264, 265, or 266.

• Calculate the organic HAP emissions reductions from the controlled web coating or printing operations using the capture and control efficiencies determined during the performance test or the materials balance for the compliance period and the total mass of organic HAP in regulated materials applied in controlled web coating and printing operations.

• Calculate the ratio of the total mass of organic HAP emissions to the total mass of solids for the regulated materials applied during the initial compliance period.

• Record the calculations and results and include them in your Notification of Compliance Status.

• Develop and implement a work practice plan to minimize emissions from storage, mixing, and handling of organic HAP-containing materials.

If you choose to comply with the organic HAP emission rate limit by using a capture system and add-on control device on a dyeing/finishing operation, other than a solvent recovery system for which you conduct a liquid-liquid material balance, you must

determine the capture and control efficiencies of the equipment. You also must determine the mass fraction of organic HAP and the mass of all dyeing and finishing materials applied during the initial compliance period. You are required to demonstrate that the capture and control system reduces organic HAP emissions to a level no greater than the applicable emission rate limit in the final rule.

If you use a solvent recovery system for which you conduct a liquid-liquid material balance, you are required to demonstrate that the solvent recovery system reduces organic HAP emissions to a level no greater than the applicable emission rate limit.

The testing and initial compliance requirements associated with determining the OCE of the capture system and add-on control device are summarized in the following paragraphs.

If you use a capture system and add-on control device, other than a solvent recovery system for which you conduct material balances, you are required to conduct an initial performance test to determine the capture and control efficiencies of the equipment and to establish operating limits to be achieved on a continuous basis. The performance test must be completed no later than 180 days after the compliance date for affected sources. To demonstrate compliance with the applicable emission rate limit with add-on controls, you must schedule the performance test in time to obtain the results for use in calculating your emission rate for the initial compliance period.

You must determine both the efficiency of the capture system and the organic HAP emission reduction efficiency of the add-on control device. To determine the capture efficiency, you must either verify the presence of a PTE using EPA Method 204 of 40 CFR part 51, appendix M (and all materials must be applied and dried or cured within the enclosure); or use one of three protocols in the final rule to measure capture efficiency. If you have a PTE and all dyeing and finishing materials are applied and dried or cured within the enclosure and you route all exhaust gases from the enclosure to an add-on control device, then you assume 100 percent capture.

To determine the organic HAP emission reduction efficiency of the add-on control device, you must conduct measurements of the inlet and outlet gas streams. The performance test will consist of three runs, each run lasting 1 hour, using the following EPA Methods in 40 CFR part 60, appendix A:

- Method 1 or 1A for selection of the sampling sites.
- Method 2, 2A, 2C, 2D, 2F, or 2G to determine the gas volumetric flow rate.
- Method 3, 3A, or 3B for gas analysis to determine dry molecular weight. You may also use as an alternative to Method 3B, the manual method for measuring the oxygen, carbon dioxide, and carbon monoxide content of exhaust gas in ANSI/ASME PTC 19.10–1981.
- Method 4 to determine stack moisture.
- Method 25 or 25A to determine organic volatile matter concentration. Alternatively, any other test method or data that have been validated according to the applicable procedures in Method 301 of 40 CFR part 63, appendix A, and approved by the Administrator, could be used.

If you use a solvent recovery system, you may determine the OCE using a liquid-liquid material balance instead of conducting an initial performance test. If you use the material balance alternative, you are required to measure the amount of all dyeing and finishing materials applied during the initial compliance period and determine the total volatile matter contained in these materials. You must also measure the amount of volatile matter recovered by the solvent recovery system during the compliance period. Then you must compare the amount recovered to the amount used to determine the OCE. You must record the calculations and results and include them in your Notification of Compliance Status.

Additional testing and initial compliance requirements associated with demonstrating compliance using the emission rate with add-on controls option are as follows:

- Determine the mass fraction of organic HAP in each dyeing and finishing material applied and the mass of each dyeing and finishing material applied during the initial compliance period, as described previously.
- Calculate the total mass of organic HAP in all dyeing and finishing materials. You may subtract from the total mass of organic HAP the amount contained in waste materials you send to a hazardous waste treatment, storage, and disposal facility regulated under 40 CFR part 262, 264, 265, or 266. You also may subtract from the total mass of organic HAP the amount demonstrated to be discharged to wastewater and not emitted to the atmosphere, in accordance with the final rule requirements.
- Calculate the organic HAP emissions reductions from the controlled dyeing or finishing operations using the capture and control efficiencies determined during the performance test or the materials balance for the compliance period and the total mass of organic HAP in dyeing and finishing materials applied in controlled dyeing and finishing operations.
- Calculate the ratio of the total mass of organic HAP emissions to the total mass of dyeing and finishing materials applied during the initial compliance period.
- Record the calculations and results and include them in your Notification of Compliance Status.
- Develop and implement a work practice plan to minimize emissions from storage, mixing, and handling of organic HAP-containing materials.

5. *Operating Limits.* As mentioned above, you must establish operating limits as part of the initial performance test of a capture system and add-on control device, other than a solvent recovery system for which you conduct liquid-liquid material balances. The operating limits are the minimum or maximum (as applicable) values achieved for capture systems and add-on control devices during the performance test, conducted under representative conditions, that demonstrated compliance with the emission limits.

The final rule specifies the parameters to monitor for the types of add-on control devices commonly used in the industry. You are required to install, calibrate, maintain, and continuously operate all monitoring equipment according to the manufacturer's specifications and ensure that the continuous parameter monitoring systems (CPMS) meet the requirements in the final rule. If you use add-on control devices other than those identified in the final rule, you must submit the operating parameters to be monitored to the Administrator for approval. The authority to approve the parameters to be monitored is retained by EPA and is not delegated to States.

If you use a thermal or catalytic oxidizer, you must continuously monitor the appropriate temperature and record it at least every 15 minutes. For thermal oxidizers, the temperature monitor is placed in the firebox or in the duct immediately downstream of the firebox before any substantial heat exchange occurs. The operating limit is the average temperature measured during the performance test, and for each consecutive 3-hour period the average temperature must be at or above this limit. For catalytic oxidizers, temperature monitors are placed at the nearest feasible point to the inlet and outlet of the catalyst bed. The operating

limits are the average temperature at the inlet to the catalyst bed and the average temperature difference across the catalyst bed during the performance test. For each 3-hour period, the average temperature and the average temperature difference must be at or above these limits. Alternatively, you are allowed to meet only the temperature limit at the inlet to the catalyst bed if you develop and implement an inspection and maintenance plan that includes periodic catalyst activity checks.

For each capture system you must conduct monitoring according to your monitoring plan, as described previously in this preamble.

6. Work Practices. If you use a capture system and add-on control device for compliance, you are required to develop and implement on an ongoing basis a work practice plan for minimizing organic HAP emissions to the atmosphere from storage, mixing, material handling, and waste handling operations. This plan must include a description of all steps taken to minimize emissions from these sources (*e.g.*, using closed storage containers, practices to minimize emissions during filling and transfer of contents from containers, using spill minimization techniques, placing solvent-laden cloths in closed containers immediately after use, etc.). You must make the plan available for inspection if the Administrator requests to see it.

7. *Operations During Startup, Shutdown, or Malfunction.* If you use a capture system and add-on control device for compliance, you are required to develop and operate according to a SSMP during periods of startup, shutdown, or malfunction of the capture system and add-on control device.

E. What Are the Continuous Compliance Provisions?

1. *Emission Limits.* If you demonstrate compliance with the emission limits for slashing based on the materials purchased (compliant material option), you will demonstrate continuous compliance if, for each compliance period, the organic HAP content of each slashing material purchased meets the emission limits. You will use manufacturer's data to demonstrate compliance each compliance period as you did for the initial compliance period.

If you demonstrate compliance with the emission limits for web coating and printing based on the materials applied, you will demonstrate continuous compliance if, for each compliance period, either you apply only coating and printing materials that meet the applicable emission limit and only non-organic HAP thinning and cleaning materials (compliant material option); or the ratio of total mass of organic HAP to total mass of solids in coating and printing materials applied is less than or equal to the emission limits (emission rate without add-on controls option). You follow the same procedures for calculating the organic HAP to coating and printing solids ratio that you used for the initial compliance period.

If you demonstrate compliance with the emission limits for dyeing and finishing based on the materials applied, you will demonstrate continuous compliance if, for each compliance period, either the organic HAP content of each dyeing and finishing material applied meets the applicable emission limit (compliant material option) or the total mass of organic HAP in all dyeing and finishing materials applied divided by the total mass of dyeing and finishing materials applied meets the applicable emission limit (emission rate without add-on controls option). You follow the same procedures for determining the mass of organic HAP in all materials applied during the compliance period that you used for the initial compliance period.

If you demonstrate compliance with the equivalent emission rate for dyeing and finishing, you will demonstrate continuous compliance, if for each 12-month compliance period, you operate within the operating scenarios for which wastewater streams were characterized during the initial compliance period, you document that affected wastewater streams were discharged to a POTW or treated onsite in a treatment system that includes at least secondary treatment with biological treatment processes, and organic HAP emissions from the dyeing/finishing affected source are less than 10 tons per year.

For each web coating or printing operation on which you use a capture system and add-on control device, other than solvent recovery for which you conduct a liquid-liquid material balance, the continuous parameter monitoring results for each compliance period will affect your compliance determination. If the monitoring results indicate no deviations from the operating limits and there were no bypasses of the add-on control device, you would assume the capture system and add-on control device are achieving the same emission reduction as they did during the performance test in which the operating limits were established. If you are demonstrating compliance with either the organic HAP OCE option or the emission rate with add-on controls option, you would then apply the OCE to the total mass of organic HAP in regulated materials applied in controlled web coating or printing operations to determine the mass of organic HAP emissions from those operations for the compliance period. If there were any deviations from the operating limits during the compliance period or any bypasses of the add-on control device, you must account for them in the calculation of the applicable emission rate by assuming the capture system and add-on control device were achieving zero emission reduction during the periods of deviation.

For each web coating and printing operation on which you use a solvent recovery system and conduct a liquid-liquid material balance each compliance period, you will use the liquid-liquid material balance to determine the emission rate. You will be required to measure the amount of all regulated materials applied during each compliance period and determine the volatile matter content of these materials. You will also measure the amount of volatile matter recovered by the solvent recovery system during the compliance period and calculate the weight percent of organic HAP applied that was emitted to determine compliance with the organic HAP OCE option. If you are complying with the emission rate with add-on controls option, you must apply the OCE to the total mass of organic HAP in the regulated materials applied to determine total organic HAP emissions as input to the compliance demonstration.

For each dyeing and finishing operation on which you use a capture system and add-on control device, other than solvent recovery for which you conduct a liquid-liquid material balance, to comply with the emission rate with add-on controls option, the continuous parameter monitoring results for each compliance period will affect your compliance determination. If the monitoring results indicate no deviations from the operating limits and there were no bypasses of the add-on control device, you will assume the capture system and add-on control device are achieving the same emission reduction as they did during the performance test in which the operating limits were established. You will then apply the OCE to the total mass of organic HAP in dyeing and finishing materials applied in controlled dyeing and finishing operations to determine the mass of organic HAP emissions from those operations for the compliance period. If there were any deviations from the operating limits during the compliance period or any bypasses of the add-on control device, you must

account for them in the calculation of the applicable emission rate by assuming the capture system and add-on control device were achieving zero emission reduction during the periods of deviation.

For each dyeing and finishing operation on which you use a solvent recovery system and conduct a liquid-liquid material balance each compliance period, you will use the liquid-liquid material balance to determine the emission rate. You will be required to measure the amount of all dyeing and finishing materials applied during each compliance period and determine the volatile matter content of these materials. You will also measure the amount of volatile matter recovered by the solvent recovery system during the compliance period and calculate the weight percent of organic HAP used that was emitted to determine the organic HAP OCE. You must apply the OCE to the total mass of organic HAP in the dyeing and finishing materials applied to determine total organic HAP emissions as input to the compliance demonstration.

2. *Operating Limits.* If you use an emission capture system and add-on control device, the final rule requires you to achieve on a continuous basis the operating limits you establish during the performance test. If the continuous monitoring shows that the capture system and/or add-on control device are operating outside the range of values established during the performance test, you have deviated from the established operating limits.

If you operate a capture system and add-on control device with bypass lines that could allow emissions to bypass the add-on control device, you must demonstrate that organic HAP emissions collected by the capture system are routed to the add-on control device by monitoring for potential bypass of the add-on control device. You may choose from the following four monitoring procedures:

- Flow control position indicator to provide a record of whether the exhaust stream is directed to the add-on control device;
- Car-seal or lock-and-key valve closures to secure the bypass line valve in the closed position when the add-on control device is operating;
- Valve closure continuous monitoring to ensure any bypass line valve or damper is closed when the add-on control device is operating; or
- Automatic shutdown system to stop the web coating/printing or dyeing/finishing operation when flow is diverted from the add-on control device.

A deviation has occurred for any period of time the bypass monitoring procedures indicate that emissions are not routed to the add-on control device.

3. *Work Practices.* If you use an emission capture system and add-on control device for compliance, you are required to implement on an ongoing basis the work practice plan you developed during the initial compliance period. If you did not develop a plan for reducing organic HAP emissions or you do not implement the plan, this would be a deviation from the work practice standard.

4. *Operations During Startup, Shutdown, and Malfunction.* If you use a capture system and add-on control device for compliance, you are required to develop and operate according to a SSMP during periods of startup, shutdown, and malfunction of the capture system and add-on control device.

F. What Are the Notification, Recordkeeping, and Reporting Requirements?

You are required to comply with the applicable requirements in subpart A of 40 CFR part 63, as described in the final rule. The General Provisions notification requirements include: initial notifications, notification of performance test if you are complying using a capture system and add-on control device, notification of compliance status, and additional notifications required for affected sources with continuous monitoring systems. The General Provisions also require certain records and periodic reports.

1. *Initial Notifications.* If you own or operate an existing affected source, you are required to send a notification to the EPA Regional Office in the Region where your affected source is located and to your State agency no later than June 2, 2004. For new and reconstructed sources, you must send the notification within 120 days after the date of initial startup or September 26, 2003, whichever is later. The report notifies us and your State agency that you have an existing affected source that is subject to the final standards, or that you have constructed a new affected source. Thus, it allows you and the permitting authority to plan for compliance activities. You also need to send a notification of planned construction or reconstruction of a source that would be subject to the final rule and apply for approval to construct or reconstruct.

2. *Notification of Performance Test.* If you demonstrate compliance by using a capture system and add-on control device for which you do not conduct a liquid-liquid material balance, you must conduct a performance test. The performance test is required within 180 days of the compliance date for an existing affected source. For a new or reconstructed affected source, the performance test would be required no later than 180 days after initial startup or November 25, 2003, whichever is later. You must notify us (or the delegated State or local agency) at least 60 calendar days before the performance test is scheduled to begin and submit a report of the performance test results no later than 60 days after the test.

3. *Notification of Compliance Status.* You must send us a Notification of Compliance Status within 30 days after the end of the initial compliance period. In the notification, you must certify whether each affected source has complied with the final standards, identify the option(s) you used to demonstrate initial compliance, summarize the data and calculations supporting the compliance demonstration, and provide information on any deviations from the emission limits, operating limits, or other requirements.

If you elect to comply by using a capture system and add-on control device for which you conduct performance tests, you must provide the results of the tests. Your notification must also include the measured range of each monitored parameter, the operating limits established during the performance test, and information showing whether the source has complied with its operating limits during the initial compliance period.

4. *Recordkeeping Requirements.* You are required to keep records of reported information and all other information necessary to document compliance with the final rule for 5 years. As required under the General Provisions, records for the 2 most recent years must be kept on-site; the other 3 years' records may be kept off-site. Records pertaining to the design and operation of the emission control and monitoring equipment must be kept for the life of the equipment. You need to keep all documentation supporting initial notifications and notifications of compliance status. If your affected source is complying with the slashing emission limits, you are required to keep purchase records of the organic HAP content of each slashing material.

Depending on the compliance option that you choose for your affected source complying with the dyeing and finishing or web coating and printing emission limits, you must keep records of the following:

• Organic HAP content, volatile matter content, coating and printing materials solids content, and quantity of the dyeing, finishing, coating, printing, thinning, and cleaning materials used during each compliance period.

• For the equivalent emission rate option for the dyeing and finishing subcategory, documentation that your dyeing/finishing affected source operated within the operating scenarios used to demonstrate initial compliance, affected wastewater streams were discharged to a POTW or treated onsite in a treatment system that includes at least secondary treatment with biological treatment processes, and organic HAP emissions from the affected source were less than 10 tpy.

• For the emission rate (with or without add-on controls) compliance options, calculations of your emission rate for each compliance period.

If your affected source is in the web coating and printing or the dyeing and finishing subcategory and you demonstrate compliance by using a capture system and add-on control device, you would also need to keep records of the following:

• All required measurements, calculations, and supporting documentation needed to demonstrate compliance with the standards.

• All results of performance tests and parameter monitoring.

• All information necessary to demonstrate conformance with your plan for minimizing emissions from mixing, storage, and waste handling operations.

• All information necessary to demonstrate conformance with the affected source's SSMP when the plan procedures are followed.

• The occurrence and duration of each startup, shutdown, or malfunction of the emission capture system and add-on control device.

• Actions taken during startup, shutdown, and malfunction that are different from the procedures specified in the affected source's SSMP.

• Each period during which a CPMS is malfunctioning or inoperative (including out-of-control periods).

The final rule requires you to collect and keep records according to certain minimum data requirements for the CPMS. Failure to collect and keep the specified minimum data is a deviation that is separate from any emission limits, operating limits, or work practice standards.

Deviations, as determined from these records, need to be recorded and also reported. A deviation is any instance when any requirement or obligation established by the final rule including, but not limited to, the emission limits, operating limits, and work practice standards, is not met.

If you use a capture system and add-on control device to reduce organic HAP emissions, you have to make your SSMP available for inspection if the Administrator requests to see it. The plan must stay in your records for the life of the affected source or until the source is no longer subject to the final standards. If you revise the plan, you need to keep the previous superseded versions on record for 5 years following the revision.

5. *Periodic Reports.* Each reporting year is divided into two semiannual reporting periods. If no deviations occur during a semiannual reporting period, you must submit a semiannual report stating that the affected source has been in continuous compliance. If deviations occur, you must include them in the report as follows:

• Report each deviation from the emission limit.

• Report each deviation from the work practice standards if you use an emission capture system and add-on control device.

• If you use an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances, report each deviation from an operating limit and each time a bypass line diverts emissions from the add-on control device to the atmosphere.

• Report other specific information on the periods of time the deviations occurred.

You also are required to include in each semiannual report an identification of the compliance option(s) you used for each affected source and any time periods when you changed to another compliance option.

6. *Other Reports.* You are required to submit reports for periods of startup, shutdown, or malfunction of the capture system and add-on control device. If the procedures you follow during any startup, shutdown, or malfunction are inconsistent with your SSMP, you must report those procedures with your semiannual reports in addition to immediate reports required by 40 CFR 63.10(d)(5)(ii).

IV. Summary of Environmental, Energy, and Economic Impacts

The final rule will affect an estimated 135 major sources that perform coating, printing, slashing, dyeing and finishing operations. The impacts are presented relative to a baseline reflecting the level of control prior to the final rule. Due to consolidation throughout the industry, there is expected to be little growth within the printing, coating and dyeing industry during the next 5 years. Only three new coating sources and no new printing, slashing, dyeing, or finishing sources are projected. For more information on how impacts were estimated, see the docket for the final rule.

A. What Are the Air Impacts?

We estimated that compliance with the emission limits in the final rule will result in reductions of nationwide organic HAP emissions of 4,100 tpy (3,700 Megagrams per year (Mg/yr)). This represents a reduction of 60 percent from the baseline organic HAP emissions of 6,800 tpy (6,200 Mg/yr). The primary air impacts by subcategory associated with implementation of the final rule are:

Subcategory	Emissions before NESHAP (tpy)	Emissions after NESHAP (tpy)	Emission reduction (tpy)	Percent reduction (%)
Web coating and Printing	5,570	2,390	3,180	57
Dyeing and Finishing	900	160	750	83
Slashing	350	170	170	50
Source Category Nationwide Total	6,820	2,720	4,100	60

B. What Are the Cost Impacts?

We have estimated the costs related to complying with the emission limitations and meeting the monitoring, recordkeeping, and reporting requirements. The costs to comply with the emission limitations include the costs of adding or upgrading emission control systems; the increased cost of compliant, low-formaldehyde permanent press finishes; and the cost of performance testing emission control systems. We have assumed for this analysis that all sources with affected slashing and dyeing operations will comply through the use of reformulated slashing, dyeing, thinning, and cleaning materials, and that these materials can be utilized without the need for capital expenditures. Annual costs for meeting the monitoring, recordkeeping, and reporting requirements of the final rule have also been included.

To comply with the final rule, web coating and printing affected sources that are not currently in compliance will likely use either upgraded existing emission control systems or new emission control systems. We estimated the capital and annual costs of carbon adsorbers, thermal oxidizers, catalytic oxidizers and coating rooms, using model plants based on information in our facility database. We examined the current level of control reported by each source in the database to determine control measures and associated model plant costs required to achieve compliance with the final rule's emission limits. Control costs estimated for the database sources were extrapolated to nationwide totals.

The dyeing and finishing compliance options are based on the use of low-organic HAP materials. Qualitative information concerning pollution prevention measures gathered from stakeholder meetings and site visits indicated that there would be substantial costs incurred in reducing the formaldehyde content of permanent press resins. We used information collected from a research and marketing company and textile chemical suppliers to estimate the incremental cost to produce finished fabric, using a compliant resin versus a formaldehyde resin. The incremental cost was applied to the quantity of fabric estimated to currently be finished with non-compliant formaldehyde resins.

Performance testing costs for coating and printing sources using add-on control systems to comply with the final rule include the labor hours required to conduct performance testing and monitoring on each emission capture system and add-on control device used and to develop the associated data elements for recordkeeping and reporting purposes. Recordkeeping and reporting includes all labor hours related to installing recordkeeping and reporting systems, developing SSMP, initial notification, compliance status notification, performance test notification, performance test report, materials usage tracking, training personnel, and monitoring deviations and SSMP reports and recordkeeping.

We estimate total capital costs to comply with the emission standards for the approximately 135 existing major sources to be $18.8 million, and nationwide annualized costs to be $14.5 million. These nationwide annualized costs include approximately $5.6 million associated with add-on control systems for web coating and printing operations, $7.5 million in costs associated with finishing material usage, and $1.4 million in monitoring, reporting, and recordkeeping costs.

The only new source costs will be for the three projected new coating sources. We have assumed that new coating sources will not install controls beyond those required for new source review, and these controls will meet the new source limit in the final rule. Therefore, we have assumed that these sources will not incur capital costs as a result of the final rule. The annual costs to comply with the monitoring, recordkeeping, and reporting requirements in the final rule for these new sources are estimated at $13,000.

C. What Are the Economic Impacts?

We prepared an economic impact analysis to evaluate the impacts the final rule would have on the producers and consumers of fabric and other textiles coating, printing, dyeing and finishing products, and society as a whole. The economic analysis determines total social costs, which take into account changes in behavior by producers, consumers, and foreign competitors of fabric products due to the imposition of compliance costs from the final rule.

Based on comments submitted by the industry, we modified our economic model to reflect strong international competition that may prevent domestic producers in the fabric finishing market from increasing prices. The model assumes that any change in domestic production in this market will be passed to foreign producers. The fabric coatings market is assumed to be able to increase prices to a minimal extent. Based on the estimated compliance costs of the final rule and the predicted changes in the coating and finishing markets, the estimated annualized social cost of the final rule is projected to be $14.5 million (2000 dollars).

It is projected that domestic producers in the fabric and textile industries will absorb $12.9 million out of the total social cost, while only $1.6 million will be passed through to consumers (in the fabric coatings market only). Domestic production in the fabric finishing market is predicted to decrease by 0.02 percent and, thus, transfer production to foreign producers, which represents an increase of 6.48 percent of total foreign production. With a minimal price increase in the fabric coatings market, domestic production is estimated to decrease by 0.08 percent, while foreign production is estimated to increase by 0.04 percent.

For new sources, it can be reasonably assumed that the investment decision to enter the coating, printing, dyeing and finishing industry may be slightly altered as a result of this final rule; however, other factors will weigh more heavily in this decision. For example, current economic trends have shown a continuous decline of the textile market as more manufacturing moves abroad. Only three new coating sources are projected to come online in the 5 years following promulgation of the final rule, and no additional printing, slashing, dyeing or fabric finishing sources are projected in the next 5 years. The three new coating sources that are projected to come online will incur a total of only $13,000 in annual costs to meet the requirements of the final rule.

Quantified economic impacts of the final rule on printed, dyed, and slashed fabric products were not calculated in the economic impact analysis because the compliance costs for the sources that produce these products are minimal and relate only to monitoring, recordkeeping, and reporting activities. Based on a qualitative analysis of the printing, dyeing, and slashing markets, we have determined that the impact on the prices and quantities of these products would be insignificant. For more information, refer to the ''Economic Impact Analysis of the Final Textile Coating, Printing, Dyeing and Finishing NESHAP'' in the docket for the final rule.

D. What Are the Non-Air Health, Environmental, and Energy Impacts?

Based on information from industry survey responses, we found no indication that the use of low-organic HAP content coating, printing, slashing, dyeing, finishing, thinning, and cleaning materials at existing sources will result in any increase or decrease in non-air health, environmental, and energy impacts. There will be no change

in the utility requirements associated with the use of these materials, so there will be no change in the amount of energy consumed as a result of the material conversion. Also, there will be no significant change in the amount of materials used or the amount of waste produced.

Non-air environmental and energy impacts will result from the installation of new and the upgrade of existing add-on controls by affected sources in the web coating and printing subcategory. Affected sources adding carbon adsorber systems will require increased cooling water usage for the condenser used to recover organic HAP from the regenerated carbon, and in certain situations for spray towers to cool the gas entering the carbon adsorber. The estimated increase in nationwide total cooling water usage will be 70.3 million gallons per year. The cooling water is assumed not to result in wastewater. There will be a small increase in water usage for steam to regenerate carbon. The steam used to regenerate carbon yields water requiring wastewater treatment. The estimated increase in nationwide total wastewater generation will be 3.8 million gallons per year.

Affected sources using existing catalytic oxidizers to comply with the final rule probably will be required to install larger volumes of catalysts and to replace the catalysts more frequently than current replacement cycles to maintain high performance levels, resulting in a small increase in solid waste generation. Similarly, affected sources that currently do not operate emission control systems and that install catalytic oxidizers to comply with the final rule will increase solid waste generation. Sometimes the spent catalyst is regenerated by the manufacturer for reuse. Activated carbon used in carbon adsorbers is returned to the manufacturer at the end of its useful life and converted to other salable products. Little solid waste impact is expected from this source.

Energy requirements for implementation of the compliance options for web coating and printing affected sources will include electricity to collect and treat ventilation air, electricity to light PTE, and natural gas to provide supplemental fuel for stable operation of oxidizers. The estimated increase in nationwide total electricity usage will be almost 2.8 million kilowatt hours per year, and the estimated nationwide total natural gas usage will increase by about 195 million standard cubic feet per year.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is ''significant'' and, therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligation of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that the final rule is not a ''significant regulatory action'' under the terms of Executive Order 12866, and is therefore not subject to OMB review.

B. Paperwork Reduction Act

The information collection requirements in the final rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 2071.02) and a copy may be obtained from Susan Auby by mail at the Collection Strategies Division (2822T), U.S. EPA, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, by e-mail at *auby.susan@epa.gov*, or by calling (202) 566–1672. A copy may also be downloaded off the Internet at *http://www.epa.gov/icr.* The information requirements are not enforceable until OMB approves them.

The information requirements are based on notification, recordkeeping, and reporting requirements in the General Provisions (40 CFR part 63, subpart A), which are mandatory for all operators subject to national emission standards. These recordkeeping and reporting requirements are specifically authorized by section 114 of the CAA (42 U.S.C. 7414). All information submitted to EPA pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to Agency policies set forth in 40 CFR part 2, subpart B.

The final rule requires maintaining records of all coating, printing, slashing, dyeing, finishing, thinning, and cleaning materials data and calculations used to determine compliance. This information includes the amount (kg) used during each monthly compliance period, mass fraction organic HAP, and, for coating and printing materials only, mass fraction of solids.

If an add-on control device is used, records must be kept of the capture efficiency of the capture system, destruction or removal efficiency of the add-on control device, and the monitored operating parameters. In addition, records must be kept of each calculation of the affected sourcewide emissions for each compliance period and all data, calculations, test results, and other supporting information used to determine this value.

The annual public monitoring, recordkeeping, and reporting burden for this collection (averaged over the first 3 years after May 29, 2003 is estimated to total 213 labor hours per affected source at a total annual cost of $1.4 million. This estimate includes, for affected sources with existing or newly-installed add-on control systems, a one-time performance test and report (with repeat tests where needed), one-time submission of a SSMP with semiannual reports for any event when the procedures in the plan were not followed, semiannual compliance status reports, and recordkeeping. There are no capital/startup costs associated with the monitoring requirements.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information

unless it displays a currently valid OMB control number. The OMB control numbers for EPA's rules are listed in 40 CFR part 9 and 48 CFR chapter 15. The OMB control number for the information collection requirements in this final rule will be listed in an amendment to 40 CFR part 9 in a subsequent **Federal Register** document after OMB approves the ICR.

C. Regulatory Flexibility Act

The EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with the final rule. The EPA has also determined that the final rule will not have a significant economic impact on a substantial number of small entities. For the purposes of assessing the impacts of today's final rule on small entities, small entity is defined as: (1) A small business according to Small Business Administration (SBA) size standards by NAICS code ranging from 500 to 1,000 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

We applied the definition of a small business as provided by the SBA at 13 CFR 121, and classified by the NAICS. The firms owning sources directly affected by the final rule are generally classified by the NAICS codes 313210 (Broadwoven Fabric Mills), 313311 (Broadwoven Fabric Finishing Mills), 313320 (Fabric Coating Mills), and 313312 (Textile and Fabric Finishing (except Broadwoven Fabric) Mills).

The SBA defines small businesses in NAICS codes 313210, 313311, and 313320 as those with fewer than 1,000 employees (as described in (1) above). In NAICS code 313312, the SBA defines a small business as one with fewer than 500 employees. In the past several years, production in the textile manufacturing industry has become more capital intensive, thus utilizing smaller numbers of employees. This leads a substantial fraction of the companies in the fabric and other textiles coating, printing, finishing, dyeing, and slashing source category to be considered small businesses based on SBA's small business size standards.

After considering the economic impacts of today's final rule on small entities, EPA has concluded that this action will not have a significant impact on a substantial number of small entities. We have identified 40 small companies classified as owning coating operations by NAICS 313320. Of these 40 small coating companies, 22 (55 percent) are projected to face zero compliance costs. Fifteen (37.5 percent) face costs less than 1 percent of their sales, and two (5 percent) have cost-to-sales ratios between 1 and 3 percent. One (2.5 percent) of these companies has a cost-to-sales ratio that exceeds 3 percent (3.2 percent).

For the dyeing and finishing subcategory, the engineering analysis determined that at most five finishing businesses representing seven facilities, would face positive compliance costs in order to meet the requirements specified by the final rule. Of these five firms, we were able to identify one company as large. Therefore, four small businesses face compliance costs associated with the final rule.

We did not possess sufficient data to identify the five finishing facilities expected to face compliance costs, so the small business analysis for finishers consisted of a sensitivity analysis of cost-to-sales ratios using minimum, mean, median, and maximum estimated compliance costs for finishing facilities. Sales data were available for 58 percent of all small entities subject to the final rule. Using median compliance cost estimates for finishing sources, we found that three companies had cost-to-sales ratios between 1 and 3 percent and none had a cost-to-sales ratio exceeding 3 percent.

For the small and large companies that engage in dyeing and slashing, compliance costs are limited to monitoring, recordkeeping, and reporting costs. Based on a qualitative analysis, we conclude that the cost will be minimal.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that the final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. The maximum total annualized cost of the final rule for any year has been estimated to be $14.5 million. Thus, today's final rule is not subject to the requirements of sections 202 and 205 of the UMRA. In addition, EPA has determined that the final rule contains no regulatory requirements that might significantly or uniquely affect small governments because it contains no requirements that apply to such governments or impose obligations upon them. Therefore, today's final rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

The final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national

government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. It has been determined that the final rule does not have ''federalism implications'' because it does not meet the necessary criteria. Thus, Executive Order 13132 does not apply to the final rule. Although section 6 of Executive Order 13132 does not apply to the rule, EPA did consult with State and local officials to enable them to provide timely input in the development of the final rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' The final rule does not have tribal implications, as specified in Executive Order 13175. No tribal governments own or operate printing, coating, and dyeing affected sources. Thus, Executive Order 13175 does not apply to the final rule.

G. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. The final rule is not subject to Executive Order 13045 because it is based on technology performance and not on health or safety risks. Furthermore, the rule has been determined not to be ''economically significant'' as defined under Executive Order 12866.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

The final rule is not subject to Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law No. 104–113, § 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The VCS are technical standards (*e.g.*, material specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency does not use available and applicable VCS.

This rulemaking involves technical standards. The EPA cites the following standards in this final rule: EPA Methods 1, 1A, 2, 2A, 2C, 2D, 2F, 2G, 3, 3A, 3B, 4, 24, 25, 25A, 204, 204A through F, and 311. Consistent with the NTTAA, EPA conducted searches to identify VCS in addition to these EPA methods. No applicable VCS were identified for EPA Methods 1A, 2A, 2D, 2F, 2G, 204, 204A through F and 311. The search and review results have been documented and are placed in the docket (Docket ID No. OAR–2003–0014, formerly Docket No. A–97–51) for the final rule.

The VCS ANSI/ASME PTC 19.10–1981, ''Flue and Exhaust Gas Analyses'' [Part 10, Instruments and Apparatus],'' is cited in this rule for its manual method for measuring the oxygen, carbon dioxide, and carbon monoxide content of exhaust gas. This part of ANSI/ASME PTC 19.10–1981, Part 10, is an acceptable alternative to Method 3B.

Six VCS: ASTM D1475–90, ASTM D2369–95, ASTM D3792–91, ASTM D4017–96a, ASTM D4457–85 (Reapproved 1991), and ASTM D5403–93 are already incorporated by reference (IBR) in EPA Method 24. Five VCS: ASTM D1979–91, ASTM D3432–89, ASTM D4747–87, ASTM D4827–93, and ASTM PS 9–94 are IBR in EPA Method 311.

The search for emissions measurement procedures identified 16 other VCS. The EPA has not adopted these standards as alternatives in the final rule. The use of these VCS would be impractical or inconsistent with applicable law due to lack of equivalency, detail, quality assurance/quality control requirements or because they are still under development. Our search and review results are available in the docket (Docket ID No. OAR–2003–0014, formerly Docket No. A–97–51).

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of the final rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). The rule will be effective May 29, 2003.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: February 28, 2003.

Christine Todd Whitman,

Administrator.

■ For the reasons stated in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

■ 2. Section § 63.14 is amended by revising paragraph (i)(3). The revision reads as follows:

§ 63.14 Incorporations by reference.

* * * * *

(i) * * *

(3) ANSI/ASME PTC 19.10–1981, ''Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus],'' IBR approved for §§ 63.865(b), 63.3360(e)(1)(iii), 63.4166(a)(3), § 63.4362(a)(3), § 63.4766(a)(3), 63.4965(a)(3), § 53.5160(d)(1)(iii), 63.9307(c)(2), and 63.9323(a)(3).

* * * * *

■ 3. Part 63 is amended by adding subpart OOOO to read as follows:

Subpart OOOO—National Emission Standards for Hazardous Air Pollutants: Printing, Coating, and Dyeing of Fabrics and Other Textiles

What This Subpart Covers

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63.4280 What is the purpose of this subpart?
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Compliance Requirements for the Compliant Material Option

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Compliance Requirements for the Emission Rate With Add-On Controls Option

63.4340 By what date must I conduct performance tests and other initial compliance demonstrations?
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63.4342 How do I demonstrate continuous compliance with the emission limitations?

Compliance Requirements for the Organic HAP Overall Control Efficiency and Oxidizer Outlet Organic HAP Concentration Options

63.4350 By what date must I conduct performance tests and other initial compliance demonstrations?
63.4351 How do I demonstrate initial compliance?
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Performance Testing and Monitoring Requirements

63.4360 What are the general requirements for performance tests?
63.4361 How do I determine the emission capture system efficiency?
63.4362 How do I determine the add-on control device emission destruction or removal efficiency?
63.4363 How do I establish the add-on control device operating limits during the performance test?
63.4364 What are the requirements for CPMS installation, operation, and maintenance?

Other Requirements and Information

63.4370 Who implements and enforces this subpart?
63.4371 What definitions apply to this subpart?

Tables to Subpart OOOO of Part 63

Table 1 to Subpart OOOO of Part 63. Emission Limits for New or Reconstructed and Existing Affected Sources in the Printing, Coating, and Dyeing of Fabrics and Other Textiles Source Category
Table 2 to Subpart OOOO of Part 63. Operating Limits if Using Add-On Control Devices and Capture System
Table 3 to Subpart OOOO of Part 63. Applicability of General Provisions to Subpart OOOO
Table 4 to Subpart OOOO of Part 63. Default Organic HAP Mass Fraction for Solvents and Solvent Blends
Table 5 to Subpart OOOO of Part 63. Default Organic HAP Mass Fraction for Petroleum Solvent Groups

Subpart OOOO—National Emission Standards for Hazardous Air Pollutants: Printing, Coating, and Dyeing of Fabrics and Other Textiles

What This Subpart Covers

§ 63.4280 What is the purpose of this subpart?

This subpart establishes national emission standards for hazardous air pollutants (NESHAP) for fabric and other textiles printing, coating and dyeing operations. This subpart also establishes requirements to demonstrate initial and continuous compliance with the emission limitations.

§ 63.4281 Am I subject to this subpart?

(a) Except as provided in paragraphs (c) and (d) of this section, the source category to which this subpart applies is the printing, coating, slashing, dyeing or finishing of fabric and other textiles, and it includes the subcategories listed in paragraphs (a)(1) through (3) of this section.

(1) The coating and printing subcategory includes any operation that coats or prints fabric or other textiles. Coating and printing operations are defined in § 63.4371. Coated and printed substrates are used in products including, but not limited to, architectural structures, apparel, flexible hoses, hot-air balloons, lightweight liners, luggage, military fabric, rainwear, sheets, tents, threads and V-belts. The coating and printing subcategory includes any fabric or other textile web coating line that also performs coating on another substrate unless such coating is specifically excluded from this subpart by another NESHAP in this part or is exempted from the requirements of this subpart based on the criteria in paragraph (e) of this section. Web coating lines exclusively dedicated to coating or printing fabric and other textiles are subject to this subpart.

(2) The slashing subcategory includes any operation with slashing operations as defined in § 63.4371. In the slashing process, sizing compounds are applied to warp yarn to bind the fiber together and stiffen the yarn to provide abrasion resistance during weaving.

(3) The dyeing and finishing subcategory includes any operation that dyes or finishes a fabric or other textiles. Dyeing and finishing operations are defined in § 63.4371. Dyed and finished textiles are used in a wide range of products including, but not limited to, apparel, carpets, high-performance industrial fabrics, luggage, military fabrics, outer wear, sheets, towels, and threads.

(b) You are subject to this subpart if you own or operate a new, reconstructed, or existing affected source, as defined in § 63.4282, that is a major source, is located at a major source, or is part of a major source of hazardous air pollutants (HAP). Major source is defined in § 63.2 of this part.

(c) This subpart does not apply to coating, printing, slashing, dyeing, or finishing operations that meet any of the

criteria of paragraphs (c)(1) through (5) of this section.

(1) Coating and printing, slashing, or dyeing and finishing operations conducted at a source that uses only regulated materials that contain no organic HAP as defined in § 63.4371.

(2) Coating, printing, slashing, dyeing, or finishing that occurs at research or laboratory operations or that is part of janitorial, building, and facility maintenance operations.

(3) Coating, printing, slashing, dyeing, or finishing operations used by a facility and not for commerce, unless organic HAP emissions from the coating, printing, slashing, dyeing or finishing operations are as high as the major source HAP emissions specified in paragraph (b) of this section.

(4) Fabric and other textile substrate web coating or printing operations conducted at ambient temperatures that do not involve drying or curing equipment such as ovens, tenter frames, steam cans, or dryers.

(5) Coating, printing, slashing, dyeing, or finishing operations performed on-site at installations owned or operated by the Armed Forces of the United States (including the Coast Guard and the National Guard of any State).

(d) Web coating lines specified in paragraphs (d)(1) through (3) of this section are not part of the affected source of this subpart.

(1) Any web coating operation that is part of the affected source of subpart JJJJ of this part (national emission standards for hazardous air pollutants for paper and other web coating). This would include any web coating line that coats both a paper and other web substrate and a fabric or other textile substrate for use in flexible packaging, pressure sensitive tape and abrasive materials, or any web coating line laminating a fabric substrate to paper.

(2) Any web coating operation that is part of the affected source of subpart XXXX of this part (NESHAP for tire manufacturing). This would include any web coating line that applies coatings to both tire cord and to textile cord used in the production of belts and hoses.

(3) Coating, slashing, dyeing, or finishing operations at a synthetic fiber manufacturing facility included in the affected source of another subpart of this part, such as subpart F (NESHAP for the synthetic organic chemical manufacturing industry) or subpart JJJ (NESHAP for group IV polymers and resins).

(e) Any web coating line that coats both fabric and other textiles, and another substrate such as paper, must comply with the subpart of this part that applies to the predominant activity conducted on the affected source. Predominant activity for this subpart is 90 percent of the mass of substrate coated during the compliance period. (For example, a web coating line that coats 90 percent or more of a paper substrate, and 10 percent or less of a fabric or other textile substrate, would be subject to 40 CFR 63, subpart JJJJ.)

§ 63.4282 What parts of my plant does this subpart cover?

(a) This subpart applies to each new, reconstructed, and existing affected source within each of the three subcategories listed in § 63.4281(a).

(b) The affected source for the web coating and printing subcategory is the collection of all of the items listed in paragraphs (b)(1) through (5) of this section that are used in fabric and other textiles web coating and printing operations. The regulated materials for the web coating and printing subcategory are the coating, printing, thinning and cleaning materials used in the affected source.

(1) All web coating and printing equipment used to apply cleaning materials to a substrate on the coating or printing line to prepare it for coating or printing material application, to apply coating or printing materials to a substrate and to dry or cure the coating or printing materials, or equipment used to clean web coating/printing operation equipment;

(2) All containers used for storage and vessels used for mixing coating, printing, thinning, or cleaning materials;

(3) All equipment and containers used for conveying coating, printing, thinning, or cleaning materials;

(4) All containers used for storage, and all equipment and containers used for conveying waste materials generated by a coating or printing operation; and

(5) All equipment, structures, and/or devices(s) used to convey, treat, or dispose of wastewater streams or residuals generated by a coating or printing operation.

(c) The affected source for the slashing subcategory is the collection of all of the items listed in paragraphs (c)(1) through (5) of this section that are used in slashing operations. The regulated materials for the slashing subcategory are the slashing materials used in the affected source.

(1) All slashing equipment used to apply and dry size on warp yarn;

(2) All containers used for storage and vessels used for mixing slashing materials;

(3) All equipment and containers used for conveying slashing materials;

(4) All containers used for storage and all equipment and containers used for conveying waste materials generated by a slashing operation; and

(5) All equipment, structures, and/or devices(s) used to convey, treat, or dispose of wastewater streams or residuals generated by a slashing operation.

(d) The affected source for the dyeing and finishing subcategory is the collection of all of the items listed in paragraphs (d)(1) through (5) of this section that are used in dyeing and finishing operations. The regulated materials for the dyeing and finishing subcategory are the dyeing and finishing materials used in the affected source.

(1) All dyeing and finishing equipment used to apply dyeing or finishing materials, to fix dyeing materials to the substrate, to rinse the textile substrate, or to dry or cure the dyeing or finishing materials;

(2) All containers used for storage and vessels used for mixing dyeing or finishing materials;

(3) All equipment and containers used for conveying dyeing or finishing materials;

(4) All containers used for storage, and all equipment and containers used for conveying, waste materials generated by a dyeing or finishing operation; and

(5) All equipment, structures, and/or devices(s) used to convey, treat, or dispose of wastewater streams or residuals generated by a dyeing or finishing operation.

(e) An affected source is a new source if it meets the criteria in paragraph (e)(1) of this section and the criteria in either paragraph (e)(2) or (3) of this section.

(1) You commenced the construction of the source after July 11, 2002.

(2) The web coating and printing, slashing, or dyeing and finishing operation is performed at a source where no web coating and printing, slashing, or dyeing and finishing operation was previously performed.

(3) The web coating and printing, slashing, or dyeing and finishing operation is performed in a subcategory in which no web coating and printing, slashing, or dyeing and finishing operation was previously performed.

(f) An affected source is reconstructed if you meet the criteria as defined in § 63.2.

(g) An affected source is existing if it is not new or reconstructed.

§ 63.4283 When do I have to comply with this subpart?

The date by which you must comply with this subpart is called the compliance date. The compliance date for each type of affected source is specified in paragraphs (a) through (c) of this section. The compliance date begins

the initial compliance period during which you conduct the initial compliance demonstration described in §§ 63.4320, 63.4330, 63.4340, and 63.4350.

(a) For a new or reconstructed affected source, the compliance date is the applicable date in paragraph (a)(1) or (2) of this section:

(1) If the initial startup of your new or reconstructed affected source is before May 29, 2003, the compliance date is May 29, 2003.

(2) If the initial startup of your new or reconstructed affected source occurs after May 29, 2003, the compliance date is the date of initial startup of your affected source.

(b) For an existing affected source, the compliance date is the date 3 years after May 29, 2003.

(c) For an area source that increases its emissions or its potential to emit such that it becomes a major source of HAP emissions, the compliance date is specified in paragraphs (c)(1) and (2) of this section.

(1) For any portion of the source that becomes a new or reconstructed affected source subject to this subpart, the compliance date is the date of initial startup of the affected source or May 29, 2003, whichever is later.

(2) For any portion of the source that becomes an existing affected source subject to this subpart, the compliance date is the date 1 year after the area source becomes a major source or 3 years after May 29, 2003, whichever is later.

(d) You must meet the notification requirements in § 63.4310 according to the dates specified in that section and in subpart A of this part. Some of the notifications must be submitted before the compliance dates described in paragraphs (a) through (c) of this section.

Emission Limitations

§ 63.4290 What emission limits must I meet?

You must meet the emission limit for the subcategory or subcategories present in your facility. The three subcategories are: Web coating and printing, slashing, and dyeing and finishing. Table 1 to this subpart presents the emission limits for a new or reconstructed affected source and for an existing affected source in each subcategory.

§ 63.4291 What are my options for meeting the emission limits?

You must include all regulated materials (as defined in § 63.4371) used in the affected source when determining whether the organic HAP emission rate is equal to or less than the applicable emission limit in Table 1 to this subpart. To make this determination, you must use at least one of the compliance options for the subcategory listed in paragraphs (a) through (c) of this section.

(a) *Web coating and printing.* You may apply any one of the compliance options in paragraphs (a)(1) through (5) of this section to an individual web coating/printing operation, or to multiple web coating/printing operations in the affected source as a group, or to the entire affected source in the web coating and printing subcategory. You may use different compliance options for different web coating/printing operations or at different times on the same web coating/printing operation. However, you may not use different compliance options at the same time on the same web coating/printing operation. If you switch between compliance options for any web coating/printing operation or group of operations, you must document this switch as required by § 63.4312(c), and you must report it in the next semiannual compliance report required in § 63.4311.

(1) *Compliant material option.* Demonstrate that the organic HAP content, as purchased, of each coating and printing material applied in the web coating/printing operation(s) is less than or equal to the applicable emission limit in Table 1 to this subpart, and that each thinning and cleaning material as purchased contains no organic HAP (as defined in § 63.4371). You must meet all the requirements of §§ 63.4320, 63.4321, and 63.4322 to demonstrate compliance with the applicable emission limit using this option.

(2) *Emission rate without add-on controls option.* Demonstrate that, based on the regulated materials applied in the web coating/printing operation(s), the organic HAP emission rate for the web coating/printing operation(s) is less than or equal to the applicable emission limit in Table 1 to this subpart, calculated as a rolling 12-month average emission rate. You must meet all the requirements of §§ 63.4330, 63.4331, and 63.4332 to demonstrate compliance with the applicable emission limit using this option.

(3) *Emission rate with add-on controls option.* Demonstrate that, based on the regulated materials applied in the web coating/printing operation(s) and the organic HAP emissions reductions achieved by emission capture systems and add-on controls, the organic HAP emission rate for the web coating/printing operation(s) is less than or equal to the applicable emission limit in Table 1 to this subpart, calculated as a rolling 12-month average emission rate. If you use this compliance option, you must also demonstrate that all capture systems and control devices for the web coating/printing operation(s) meet the operating limits required in § 63.4292, except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4341(e)(5), and that you meet the work practice standards required in § 63.4293. You must meet all the requirements of §§ 63.4340 through 63.4342 and 63.4360 through 63.4364 to demonstrate compliance with the emission limits, operating limits, and work practice standards using this option.

(4) *Organic HAP overall control efficiency option.* Demonstrate that, based on the organic HAP emission capture and add-on control efficiencies achieved, the organic HAP overall control efficiency is greater than or equal to the applicable organic HAP overall control efficiency limit in Table 1 to this subpart. If you use this compliance option, you must also demonstrate that all capture systems and control devices for the web coating/printing operation(s) meet the operating limits required in § 63.4292, except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4351(d)(5), and that you meet the work practice standards required in § 63.4293. You must meet all the requirements of §§ 63.4350 through 63.4352 and 63.4360 through 63.4364 to demonstrate compliance with the applicable emission limits, operating limits, and work practice standards using this option.

(5) *Oxidizer outlet organic HAP concentration limit.* If you use an oxidizer to control organic HAP emissions, demonstrate that the oxidizer is operated such that the outlet organic HAP concentration is no greater than 20 parts per million by volume (ppmv) on a dry basis, and that the efficiency of the capture system is 100 percent. If you use this compliance option, you must also demonstrate that all capture systems and oxidizers for the web coating/printing operation(s) meet the operating limits required in § 63.4292, and that you meet the work practice standards required in § 63.4293. You must meet all the requirements of §§ 63.4350 through 63.4352 and 63.4360 through 63.4364 to demonstrate compliance with the applicable emission limits, operating limits, and work practice standards using this option.

(b) *Slashing.* You must use the compliant material option to demonstrate that the mass fraction of organic HAP in each slashing material

as purchased for the slashing operation(s) is less than or equal to the applicable emission limit in Table 1 to this subpart. You must meet all the requirements of §§ 63.4320, 63.4321, and 63.4322 to demonstrate compliance with the applicable emission limit.

(c) *Dyeing and Finishing.* You may apply any one of the compliance options in paragraphs (c)(1) through (3) of this section to an individual dyeing/finishing operation, or to multiple dyeing/finishing operations in the affected source as a group, or to the entire affected source in the dyeing and finishing subcategory. You may use different compliance options for different dyeing/finishing operations or at different times on the same dyeing/finishing operation. However, you may not use different compliance options at the same time on the same dyeing/finishing operation. If you switch between compliance options for any dyeing/finishing operation or group of operations, you must document this switch as required by § 63.4312(c), and you must report it in the next semiannual compliance report required in § 63.4311. If you choose to apply the compliance option in paragraph (c)(4) to your dyeing/finishing operations, it must be applied to the entire affected source in the dyeing and finishing subcategory. You may not apply any of the compliance options in paragraphs (c)(1) through (3) of this section to any dyeing/finishing operation in the affected source if you use the equivalent emission rate limit in paragraph (c)(4) for your dyeing/finishing affected source.

(1) *Compliant material option.* Demonstrate that the mass fraction of organic HAP, as purchased, of each dyeing and finishing material applied in the dyeing/finishing operation(s) is less than or equal to the applicable emission limit in Table 1 to this subpart. You must meet all the requirements of §§ 63.4320, 63.4321, and 63.4322 to demonstrate compliance with the applicable emission limit using this option.

(2) *Emission rate without add-on controls option.* Demonstrate that, based on the dyeing and finishing materials applied in the dyeing/finishing operation(s), the organic HAP emission rate for the dyeing operation(s), the organic HAP emission rate for the finishing operation(s) or the combined organic HAP emission rate for dyeing and finishing is less than or equal to the applicable emission limit(s) in Table 1 to this subpart, calculated as a rolling 12-month average emission rate. You must meet all the requirements of §§ 63.4330, 63.4331, and 63.4332 to demonstrate compliance with the applicable emission limit(s) using this option.

(3) *Emission rate with add-on controls option.* Demonstrate that, based on the dyeing and finishing materials applied in the dyeing/finishing operation(s) and the organic HAP emissions reductions achieved by emission capture systems and add-on controls, the organic HAP emission rate for the dyeing/finishing operation(s) is less than or equal to the applicable emission limit in Table 1 to this subpart, calculated as a rolling 12-month average emission rate. If you use this compliance option, you must also demonstrate that all capture systems and control devices for the dyeing/finishing operation(s) meet the operating limits required in § 63.4292, except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4341(f)(5), and that you meet the work practice standards required in § 63.4293. You must meet all the requirements of §§ 63.4340 through 63.4342 and 63.4360 through 63.4364 to demonstrate compliance with the emission limits, operating limits, and work practice standards using this option.

(4) *Equivalent emission rate option.* Demonstrate that the dyeing and finishing affected source meets all the requirements of paragraphs (4)(i) through (iv) of this paragraph.

(i) The fraction of organic HAP applied in your dyeing/finishing affected source that is discharged to the wastewater is at least 90 percent, determined according to § 63.4331(d).

(ii) The wastewater is discharged to a POTW or onsite secondary wastewater treatment.

(iii) The total organic HAP emissions from your dyeing/finishing affected source are less than 10 tons per year, as calculated in Equation 4 of § 63.4331.

(iv) You must meet the applicable requirements of § 63.4330 and maintain records in accordance with § 63.4312(c)(2)(iv) to demonstrate compliance with the equivalent emission rate option.

§ 63.4292 What operating limits must I meet?

(a) For any web coating/printing operation, slashing operation, or dyeing/finishing operation on which you use the compliant material option; web coating/printing operation or dyeing/finishing operation on which you use the emission rate without add-on controls option; or dyeing/finishing affected source on which you use the equivalent emission rate limit option, you are not required to meet any operating limits.

(b) For any controlled web coating/printing operation or dyeing/finishing operation on which you use the emission rate with add-on controls option, or controlled web coating/printing operation on which you use the organic HAP overall control efficiency option or the oxidizer outlet organic HAP concentration option, except those web coating/printing operations for which you use a solvent recovery system and conduct a liquid-liquid material balance according to § 63.4341(e)(5) and those dyeing/finishing operations for which you use a solvent recovery system and conduct a liquid-liquid material balance according to § 63.4341(f)(5), you must meet the operating limits specified in Table 2 of this subpart. These operating limits apply to the emission capture and control systems on the web coating/printing operation(s) and dyeing/finishing operations for which you use this option, and you must establish the operating limits during the performance test according to the procedures in § 63.4363. You must meet the operating limits at all times after you establish them.

(c) If you use an add-on control device other than those listed in Table 2 of this subpart, or wish to monitor an alternative parameter and comply with a different operating limit, you must apply to the Administrator for approval of alternative monitoring under § 63.8(f).

§ 63.4293 What work practice standards must I meet?

(a) For any slashing operation, you are not required to meet any work practice standards. For any web coating/printing operation(s) or dyeing/finishing operation(s) on which you use the compliant material option or the emission rate without add-on controls option, you are not required to meet any work practice standards. For any dyeing/finishing affected source on which you use the equivalent emission rate option, you are not required to meet any work practice standards.

(b) If you use either the emission rate with add-on controls option, the organic HAP overall control efficiency option, or the oxidizer outlet organic HAP concentration option for a web coating/printing operation; or you use the emission rate with add-on controls option for a dyeing/finishing operation; you must develop and implement a work practice plan to minimize organic HAP emissions from the storage, mixing, and conveying of regulated materials used in, and waste materials generated by, the coating/printing or

dyeing/finishing operations for which you use this option; or you must meet an alternative standard as provided in paragraph (c) of this section. The plan must specify practices and procedures to ensure that, at a minimum, the elements specified in paragraphs (b)(1) through (5) of this section are implemented.

(1) All organic-HAP-containing regulated materials and waste materials must be stored in closed containers.

(2) Spills of organic-HAP-containing regulated materials, and waste materials must be minimized.

(3) Organic-HAP-containing regulated materials and waste materials must be conveyed from one location to another in closed containers or pipes.

(4) Mixing vessels which contain organic-HAP-containing regulated materials must be closed except when adding to, removing, or mixing the contents.

(5) Emissions of organic HAP must be minimized during cleaning of web coating/printing or dyeing/finishing storage, mixing, and conveying equipment.

(c) As provided in § 63.6(g), you may request approval from the Administrator to use an alternative to the work practice standards in this section.

General Compliance Requirements

§ 63.4300 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the emission limitations in this subpart as specified in paragraphs (a)(1) through (4) of this section.

(1) Any web coating/printing, slashing, or dyeing/finishing operation(s) for which you use the compliant material option, as specified in § 63.4291(a)(1), (b), or (c)(1) must be in compliance with the applicable emission limit in Table 1 to this subpart at all times.

(2) Any web coating/printing or dyeing/finishing operation(s) for which you use the emission rate without add-on controls option, as specified in § 63.4291(a)(2) or (c)(2), must be in compliance with the applicable emission limit in Table 1 to this subpart for all compliance periods.

(3) Any web coating/printing or dyeing/finishing operation(s) for which you use the emission rate with add-on controls option, as specified in § 63.4291(a)(3) or (c)(3), and any web coating/printing operation(s) for which you use either the organic HAP overall control efficiency option, as specified in § 63.4291(a)(4), or the oxidizer outlet organic HAP concentration option, as specified in § 63.4291(a)(5), must be in compliance with the emission limitations as specified in paragraphs (a)(3)(i) through (iii) of this section.

(i) The web coating/printing or dyeing/finishing operation(s) must be in compliance with the applicable emission limit in Table 1 to this subpart or comply with the startup, shutdown, and malfunction plan at all times.

(ii) Each controlled web coating/printing or dyeing/finishing operation must be in compliance with the operating limits for emission capture systems and add-on control devices required by § 63.4292 for all averaging time periods except for solvent recovery systems for which you conduct liquid-liquid material balances according to §§ 63.4341(e)(5) or (f)(5) or 63.4351(d)(5).

(iii) Each controlled web coating/printing or dyeing/finishing operation must be in compliance with the work practice standards in § 63.4293 at all times.

(4) Any dyeing/finishing affected source for which you use the equivalent emission rate option, as specified in § 63.4291(c)(4), must operate within the operating scenarios, as defined in § 63.4371, for which you determined the fraction of organic HAP applied in your dyeing/finishing affected source that is discharged to wastewater according to § 63.4331(d) at all times.

(b) You must always operate and maintain your affected source, including air pollution control and monitoring equipment, according to the provisions in § 63.6(e)(1)(i).

(c) If your affected source uses an emission capture system and add-on control device, you must develop and implement a written startup, shutdown, and malfunction plan according to the provisions in § 63.6(e)(3). The plan must address the startup, shutdown, and corrective actions in the event of a malfunction of the emission capture system or the add-on control device. The plan must also address any web coating/printing or dyeing/finishing operation equipment such as conveyors that move the substrate among enclosures that may cause increased emissions or that would affect capture efficiency if the process equipment malfunctions.

§ 63.4301 What parts of the General Provisions apply to me?

Table 3 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.15 apply to you.

Notifications, Reports, and Records

§ 63.4310 What notifications must I submit?

(a) You must submit the notifications in §§ 63.7(b) and (c), 63.8(f)(4), and 63.9(b) through (e) and (h) that apply to you by the dates specified in those sections, except as provided in paragraphs (b) and (c) of this section.

(b) *Initial Notification.* You must submit the Initial Notification required by § 63.9(b) for a new or reconstructed affected source no later than 120 days after initial startup or 120 days after May 29, 2003, whichever is later. For an existing affected source, you must submit the Initial Notification no later than 1 year after May 29, 2003.

(c) *Notification of Compliance Status.* You must submit the Notification of Compliance Status required by § 63.9(h) no later than 30 calendar days following the end of the initial compliance period described in §§ 63.4320, 63.4330, 63.4340, or 63.4350 that applies to your affected source. The Notification of Compliance Status must contain the information specified in paragraphs (c)(1) through (9) of this section and in § 63.9(h).

(1) Company name and address.

(2) Statement by a responsible official with that official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report.

(3) Date of the report and beginning and ending dates of the reporting period. The reporting period is the initial compliance period described in §§ 63.4320, 63.4330, 63.4340, or 63.4350 that applies to your affected source.

(4) Identification of the compliance option or options specified in § 63.4291 that you used during the initial compliance period on each web coating/printing operation in each web coating/printing affected source, on each slashing operation in each slashing affected source, and on each dyeing/finishing operation in each dyeing/finishing affected source.

(5) Statement of whether or not the affected source achieved the emission limitations for the initial compliance period.

(6) If you had a deviation, include the information in paragraphs (c)(6)(i) and (ii) of this section.

(i) A description, and statement of the cause of, the deviation.

(ii) If you failed to meet the applicable emission limit in Table 1 to this subpart, include all the calculations you used to determine the kilogram (kg) organic HAP emitted per kg of solids applied in coating and printing material or the weight percent organic HAP compounds

in slashing, dyeing or finishing material to demonstrate your failure to meet the applicable emission limit. You do not need to submit information provided by the materials suppliers or manufacturers or test reports.

(7) For each of the data items listed in paragraphs (c)(7)(i) through (iii) of this section that is required by the compliance option(s) you used to demonstrate compliance with the emission limit, include an example of how you determined the value, including calculations and supporting data. Supporting data can include a copy of the information provided by the supplier or manufacturer of the example regulated material or a summary of the results of testing conducted according to § 63.4321(e)(1) or (2). You do not need to submit copies of any test reports.

(i) Mass fraction of organic HAP and mass fraction of solids for one coating or printing formulation including thinning materials, mass fraction of organic HAP for one cleaning material and mass fraction of organic HAP for all of the regulated materials as purchased used in one slashing operation or dyeing/ finishing operation.

(ii) Mass of coating or printing formulation used in web coating/ printing operation or of dyeing and finishing materials used in the dyeing/ finishing operation during the compliance period.

(iii) The amount of waste materials and the mass of organic HAP contained in the waste materials for which you are claiming an allowance in Equation 1 or 4 of § 63.4331.

(iv) The mass of organic HAP in the dyeing and finishing materials applied during the compliance period and the mass of organic HAP in wastewater discharged to a POTW or receiving onsite secondary treatment for which you are claiming an allowance in Equation 4 of § 63.4331.

(8) The calculation of kg organic HAP per kg of coating and printing solids applied and of kg organic HAP per kg of dyeing and finishing material as purchased for the compliance option(s) you use, as specified in paragraphs (c)(8)(i) through (vii) of this section.

(i) For the compliant material option as specified in § 63.4291(a)(1) for web coating/printing operations, provide an example calculation of the organic HAP content for one coating and one printing material, as appropriate, using Equation 1 of § 63.4321.

(ii) For the emission rate without add-on controls option as specified in § 63.4291(a)(2) for web coating/printing operations, provide the calculation of the total mass of organic HAP emissions; the calculation of the total mass of coating and printing solids applied; and the calculation of the organic HAP emission rate, using Equations 1, 2, and 3, respectively, of § 63.4331.

(iii) For the emission rate without add-on controls option as specified in § 63.4291(c)(2) for dyeing/finishing operations, provide the calculation of the total mass of organic HAP emissions; the calculation of the total mass of dyeing and finishing materials applied; and the calculation of the organic HAP emission rate, using Equations 4, 5, and 6, respectively, of § 63.4331.

(iv) For the emission rate with add-on controls option as specified in § 63.4291(a)(3) for web coating/printing operations, provide the calculation of the total mass of organic HAP emissions before add-on controls using Equation 1 of § 63.4331, and the calculation of the organic HAP emission rate using Equation 4 of § 63.4341.

(v) For the emission rate with add-on controls option as specified in § 63.4291(c)(3) for dyeing/finishing operations, provide the calculation of the mass of organic HAP emissions before add-on controls using Equation 4 of § 63.4331, and the calculation of the organic HAP emission rate using Equation 8 of § 63.4341.

(vi) For the organic HAP overall control efficiency option as specified in § 63.4291(a)(4), provide the calculation of the total mass of organic HAP emissions before add-on controls using Equation 1 of § 63.4331 and the calculation of the organic HAP overall control efficiency using Equation 1 of § 63.4351.

(vii) For the equivalent emission rate option as specified in § 63.4291(c)(4), provide the calculation of the fraction of organic HAP applied in affected processes that is discharged to wastewater according to § 63.4331(d), the calculation of the total organic HAP emissions from your dyeing/finishing affected source using Equation 4 of § 63.4331, and documentation that organic HAP containing wastewater is either discharged to a POTW or treated onsite in a treatment system that includes at least secondary treatment.

(9) For the emission rate with add-on controls option as specified in § 63.4291(a)(3) and (c)(3), the organic HAP overall control efficiency option as specified in § 63.4291(a)(4), and the oxidizer outlet organic HAP concentration option as specified in § 63.4291(a)(5), for each controlled web coating/printing or dyeing/finishing operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances according to §§ 63.4341(e)(5) or (f)(5) or 63.4351(d)(5), you must include the information specified in paragraphs (c)(9)(i) through (iv) of this section.

(i) For each emission capture system, a summary of the data and copies of the calculations supporting the determination that the emission capture system is a permanent total enclosure (PTE) or a measurement of the emission capture system efficiency. If you are demonstrating compliance with the oxidizer outlet organic HAP concentration option, the emission capture system must be a PTE. Include a description of the protocol followed for measuring capture efficiency, summaries of any capture efficiency tests conducted, and any calculations supporting the capture efficiency determination. If you use the data quality objective (DQO) or lower confidence limit (LCL) approach, you must also include the statistical calculations to show you meet the DQO or LCL criteria in appendix A to subpart KK of this part. You do not need to submit complete test reports.

(ii) A summary of the results of each add-on control device performance test. You do not need to submit complete test reports.

(iii) A list of each emission capture system's and add-on control device's operating limits and a summary of the data used to calculate those limits.

(iv) A statement of whether or not you developed and implemented the work practice plan required by § 63.4293 and the startup, shutdown and malfunction plan required by § 63.4300.

§ 63.4311 What reports must I submit?

(a) *Semiannual compliance reports.* You must submit semiannual compliance reports for each affected source according to the requirements of paragraphs (a)(1) through (8) of this section. The semiannual compliance reporting requirements of this section may be satisfied by reports required under other parts of the Clean Air Act (CAA), as specified in paragraph (a)(2) of this section.

(1) *Dates.* Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must prepare and submit each semiannual compliance report according to the dates specified in paragraphs (a)(1)(i) through (iv) of this section.

(i) The first semiannual compliance report must cover the first semiannual reporting period which begins the day after the end of the initial compliance period described in §§ 63.4320, 63.4330,

63.4340, or 63.4350 that applies to your affected source and ends on June 30 or December 31, whichever date is the first date at least 6 months after the end of the initial compliance period.

(ii) Each subsequent semiannual compliance report must cover the subsequent semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31.

(iii) Each semiannual compliance report must be postmarked or delivered no later than July 31 or January 31, whichever date is the first date following the end of the semiannual reporting period.

(iv) For each affected source that is subject to permitting regulations pursuant to 40 CFR part 70 or 40 CFR part 71, and if the permitting authority has established dates for submitting semiannual reports pursuant to 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), you may submit the first and subsequent compliance reports according to the dates the permitting authority has established instead of according to the date specified in paragraph (a)(1)(iii) of this section.

(2) *Inclusion with title V report.* Each affected source that has obtained a title V operating permit pursuant to 40 CFR part 70 or 40 CFR part 71 must report all deviations as defined in this subpart in the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A). If an affected source submits a semiannual compliance report pursuant to this section along with, or as part of, the semiannual monitoring report required by 40 CFR 70.6(a)(3)(iii)(A) or 40 CFR 71.6(a)(3)(iii)(A), and the semiannual compliance report includes all required information concerning deviations from any emission limitation in this subpart, its submission shall be deemed to satisfy any obligation to report the same deviations in the semiannual monitoring report. However, submission of a semiannual compliance report shall not otherwise affect any obligation the affected source may have to report deviations from permit requirements to the permitting authority.

(3) *General requirements.* The semiannual compliance report must contain the information specified in paragraphs (a)(3)(i) through (v) of this section, and the information specified in paragraphs (a)(4) through (8) and (c)(1) of this section that is applicable to your affected source. If your affected source is a slashing operation(s), you are only required to report the information in paragraphs (a)(3)(i) through (iii) of this section and the information in paragraph (a)(4) or (a)(5) of this section, as applicable.

(i) Company name and address.

(ii) Statement by a responsible official with that official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report.

(iii) Date of report and beginning and ending dates of the reporting period. The reporting period is the 6-month period ending on June 30 or December 31.

(iv) Identification of the compliance option or options specified in § 63.4291 that you used on each web coating/printing and dyeing/finishing operation during the reporting period. If you switched between compliance options during the reporting period, you must report the beginning and ending dates you used each option.

(v) If you used the emission rate without add-on controls, the emission rate with add-on controls, or the organic HAP overall control efficiency compliance option for web coating/printing operations (§ 63.4291(a)(2), (3), or (4)), or the emission rate without add-on controls or the emission rate with add-on controls compliance option for dyeing/finishing operations (§ 63.4291(c)(2) or (c)(3)), the calculation results for each compliance period ending each month during the 6-month reporting period.

(4) *No deviations.* If there were no deviations from the emission limitations in Table 1 to this subpart and §§ 63.4292, and 63.4293 that apply to you, the semiannual compliance report must include a statement that there were no deviations from the emission limitations during the reporting period. If you use the emission rate with add-on controls option, the organic HAP overall control efficiency option, or the oxidizer outlet organic HAP concentration option and there were no periods during which the continuous parameter monitoring systems (CPMS) were out-of-control as specified in § 63.8(c)(7), the semiannual compliance report must include a statement that there were no periods during which the CPMS were out-of-control during the reporting period.

(5) *Deviations: compliant material option.* If you use the compliant material option, and there was a deviation from the applicable organic HAP content requirements in Table 1 to this subpart, the semiannual compliance report must contain the information in paragraphs (a)(5)(i) through (iv) of this section.

(i) Identification of each coating, printing, slashing, dyeing or finishing material applied that deviated from the emission limit and each thinning or cleaning material applied in web coating/printing operations that contained organic HAP, and the dates and time periods each was applied.

(ii) The calculation of the organic HAP content using Equation 1 of § 63.4321 for each coating or printing material identified in paragraph (a)(5)(i) of this section. You do not need to submit background data supporting this calculation (*e.g.,* information provided by material suppliers or manufacturers, or test reports).

(iii) The determination of mass fraction of organic HAP for each regulated material identified in paragraph (a)(5)(i) of this section. You do not need to submit background data supporting this calculation (*e.g.,* information provided by material suppliers or manufacturers, or test reports).

(iv) A statement of the cause of each deviation.

(6) *Deviations: emission rate without add-on controls option.* If you use the emission rate without add-on controls option and there was a deviation from the applicable emission limit in Table 1 to this subpart, the semiannual compliance report must contain the information in paragraphs (a)(6)(i) through (iii) of this section.

(i) The beginning and ending dates of each compliance period during which the organic HAP emission rate exceeded the applicable emission limit in Table 1 to this subpart.

(ii) The calculations used to determine the organic HAP emission rate for the compliance period in which the deviation occurred. You must submit the calculations for Equations 1, 1A and 1B, 2, and 3 in § 63.4331 for web coating/printing operations; and for Equations 4, 4A, 5, and 6 in § 63.4331 for dyeing/finishing operations; and if applicable, the calculation used to determine mass of organic HAP in waste materials according to § 63.4331(a)(4)(iii) or (b)(3)(ii); and, for dyeing/finishing operations, if applicable, the mass of organic HAP in wastewater streams calculation for Equation 7 in § 63.4331. You do not need to submit background data supporting these calculations (*e.g.,* information provided by materials suppliers or manufacturers, or test reports).

(iii) A statement of the cause of each deviation.

(7) *Deviations: add-on controls options.* If you use one of the add-on controls options in § 63.4291(a) or (c) and there was a deviation from an emission limitation (including any periods when emissions bypassed the

add-on control device and were diverted to the atmosphere), the semiannual compliance report must contain the information in paragraphs (a)(7)(i) through (xv) of this section. This includes periods of startup, shutdown, and malfunction during which deviations occurred.

(i) The beginning and ending dates of each compliance period during which the organic HAP emission rate exceeded the applicable emission limit in Table 1 to this subpart.

(ii) If you use the emission rate option, the calculations used to determine the organic HAP emission rate for each compliance period in which a deviation occurred. You must submit the calculations that apply to you, including Equations 1, 1A, 1B, and 2 of § 63.4331 and Equations 1, 1A, 1B, 1C, 2, 3, 3A and 3B and 4 of § 63.4341 for web coating/printing operations; and Equations 4, 4A, 5, and 7 of § 63.4331 and Equations 5, 5A, 5B, 6, 7, and 8 of § 63.4341 for dyeing/finishing operations. You do not need to submit the background data supporting these calculations (*e.g.,* information provided by materials suppliers or manufacturers, or test reports).

(iii) If you use the organic HAP overall control efficiency option, the calculations used to determine the organic HAP overall control efficiency for each compliance period in which a deviation occurred. You must submit the calculations that apply to you, including Equations 1, 1A, and 1B of § 63.4331; Equations 1, 1A, 1B, 1C, 2, 3, 3A, and 3B of § 63.4341; and Equation 1 of § 63.4351. You do not need to submit the background data supporting these calculations (*e.g.,* test reports).

(iv) The date and time that each malfunction started and stopped.

(v) A brief description of the CPMS.

(vi) The date of the latest CPMS certification or audit.

(vii) The date and time that each CPMS was inoperative, except for zero (low-level) and high-level checks.

(viii) The date, time, and duration that each CPMS was out-of-control, including the information in § 63.8(c)(8).

(ix) The date and time period of each deviation from an operating limit in Table 2 to this subpart, date and time period of any bypass of the add-on control device, and whether each deviation occurred during a period of startup, shutdown, or malfunction or during another period.

(x) A summary of the total duration of each deviation from an operating limit in Table 2 to this subpart and each bypass of the add-on control device during the semiannual reporting period and the total duration as a percent of the total source operating time during that semiannual reporting period.

(xi) A breakdown of the total duration of the deviations from the operating limits in Table 2 to this subpart and bypasses of the add-on control device during the semiannual reporting period into those that were due to startup, shutdown, control equipment problems, process problems, other known causes, and other unknown causes.

(xii) A summary of the total duration of CPMS downtime during the semiannual reporting period and the total duration of CPMS downtime as a percent of the total source operating time during that semiannual reporting period.

(xiii) A description of any changes in the CPMS, web coating/printing or dyeing/finishing operation, emission capture system, or add-on control device since the last semiannual reporting period.

(xiv) For each deviation from the work practice standards, a description of the deviation, the date and time period duration of the deviation, and the actions you took to correct the deviation.

(xv) A statement of the cause of each deviation.

(8) *Deviations: Equivalent Emission Rate Option.* If you use the equivalent emission rate option, and there was a deviation from the operating scenarios, as defined in § 63.4371, used to demonstrate initial compliance, the semiannual compliance report must contain the information in paragraphs (a)(i) through (iv) of this section.

(i) The beginning and ending dates of each compliance period during which the deviation occurred.

(ii) If the deviation consisted of failure to treat the organic HAP containing wastewater by a biological treatment process, an explanation of the deviation, the duration of the deviation, and the determination of the mass of organic HAP that was discharged in the wastewater that was not treated by a biological treatment process.

(iii) The determination of the fraction of organic HAP applied in your dyeing/finishing affected source that is discharged to the wastewater according to § 63.4331(d).

(iv) The calculation of the total organic HAP emissions from your dyeing/finishing affected source using Equation 4 of § 63.4331.

(b) *Performance test reports.* If you use one of the add-on control options in § 63.4291(a) or (c), you must submit reports of performance test results for emission capture systems and add-on control devices no later than 60 days after completing the tests as specified in § 63.10(d)(2).

(c) *Startup, shutdown, malfunction reports.* If you use one of the add-on control options in § 63.4291(a) or (c) and you have a startup, shutdown, or malfunction during the semiannual reporting period, you must submit the reports specified in paragraphs (c)(1) and (2) of this section.

(1) If your actions were consistent with your startup, shutdown, and malfunction plan, you must include the information specified in § 63.10(d) in the semiannual compliance report.

(2) If your actions were not consistent with your startup, shutdown, and malfunction plan, you must submit an immediate startup, shutdown, and malfunction report as described in paragraphs (c)(2)(i) and (ii) of this section as required by paragraph (a) of this section.

(i) You must describe the actions taken during the event in a report delivered by facsimile, telephone, or other means to the Administrator within 2 working days after starting actions that are inconsistent with the plan.

(ii) You must submit a letter to the Administrator within 7 working days after the end of the event, unless you have made alternative arrangements with the Administrator as specified in § 63.10(d)(5)(ii). The letter must contain the information specified in § 63.10(d)(5)(ii).

§ 63.4312 What records must I keep?

You must collect and keep a record of the data and information specified in this section. Failure to collect and keep these records is a deviation from the applicable standard.

(a) A copy of each notification and report that you submitted to comply with this subpart, and the documentation supporting each notification and report.

(b) A current copy of information provided by materials suppliers or manufacturers, such as manufacturer's formulation data or test data used to determine the mass fraction of organic HAP for coating, printing, slashing, dyeing, finishing, thinning, and cleaning materials; and the mass fraction of solids for coating and printing materials. If you conducted testing to determine mass fraction of organic HAP of coating materials or the mass fraction of solids of coating materials, you must keep a copy of the complete test report. If you use information provided to you by the manufacturer or supplier of the material that was based on testing, you must keep the summary sheet of results provided to you by the manufacturer or

supplier. You are not required to obtain the test report or other supporting documentation from the manufacturer or supplier.

(c) For each compliance period, the records specified in paragraph (c)(1) of this section for web coating/printing operations and the records specified in paragraph (c)(2) of this section for dyeing/finishing operations.

(1) A record of the web coating/printing operations on which you used each compliance option and the time periods (beginning and ending dates) you used each option. For each month, a record of all required calculations for the compliance option(s) you used, as specified in paragraphs (c)(1)(i) through (iv) of this section.

(i) For the compliant material option, a record of the calculation of the organic HAP content, as purchased, for each coating and printing material applied, using Equation 1 of § 63.4321.

(ii) For the emission rate without add-on controls option, a record of the calculation of the total mass of organic HAP emissions for the coating, printing, thinning and cleaning materials applied each compliance period using Equations 1, 1A, and 1B of § 63.4331 and, if applicable, the calculation used to determine the mass of organic HAP in waste materials according to § 63.4331(a)(4)(iii); the calculation of the total mass of the solids contained in all coating and printing materials applied each compliance period using Equation 2 of § 63.4331; and the calculation of the organic HAP emission rate for each compliance period using Equation 3 of § 63.4331.

(iii) For the emission rate with add-on controls option, a record of the calculation of the total mass of organic HAP emissions before add-on controls for the coating, printing, thinning and cleaning materials applied each compliance period using Equations 1, 1A, and 1B of § 63.4331 and, if applicable, the calculation used to determine the mass of organic HAP in waste materials according to § 63.4331(a)(4)(iii); the calculation of the total mass of the solids contained in all coating and printing materials applied each compliance period using Equation 2 of § 63.4331; the calculation of the mass of organic HAP emission reduction by emission capture systems and add-on control devices using Equations 1, 1A, 1B, and 1C of § 63.4341 and Equations 2, 3, 3A, and 3B of § 63.4341, as applicable; and the calculation of the organic HAP emission rate for each compliance period using Equation 4 of § 63.4341.

(iv) For the organic HAP overall control efficiency option or the oxidizer outlet organic HAP concentration option, the records specified in paragraph (j) of this section.

(2) A record of the dyeing/finishing operations on which you used each compliance option and the time periods (beginning and ending dates) you used each option. For each month, a record of all required calculations for the compliance option(s) you used, as specified in paragraphs (c)(2)(i) through (iv) of this section.

(i) For the compliant material option, a purchase record of the mass fraction of organic HAP for each dyeing, and finishing material applied, according to § 63.4321(e)(1)(iv).

(ii) For the emission rate without add-on controls option, the calculation for the total mass of organic HAP emissions for the dyeing and finishing materials applied each compliance period using Equations 4 and 4A of § 63.4331 and, if applicable, the calculations used to determine the mass of organic HAP in waste materials according to § 63.4331(b)(3)(ii) and the mass of organic HAP contained in wastewater discharged to a POTW or treated onsite prior to discharge according to § 63.4331(b)(3)(iii); the calculation of the total mass of dyeing and finishing materials applied each compliance period using Equation 5 of § 63.4331; and the calculation of the organic HAP emission rate for each compliance period using Equation 6 of § 63.4331.

(iii) For the emission rate with add-on controls option, a record of the calculation of the total mass of organic HAP emissions before add-on controls for the dyeing and finishing materials applied each compliance period using Equations 4 and 4A of § 63.4331 and, if applicable, the calculation used to determine the mass of organic HAP in waste materials according to § 63.4331(b)(3)(ii) and the determination of the mass of organic HAP contained in wastewater discharged to a POTW or treated onsite prior to discharge according to § 63.4331(b)(3)(iii); the calculation of the total mass of dyeing and finishing materials applied each compliance period using Equation 5 of § 63.4331; the calculation of the mass of organic HAP emission reduction by emission capture systems and add-on control devices using Equations 5, 5A, and 5B of § 63.4341 and Equations 6, 7, and 7A of § 63.4341, as applicable; and the calculation of the organic HAP emission rate for each compliance period using Equation 8 of § 63.4341.

(iv) For the equivalent emission rate option, a record that your dyeing/finishing affected source operated within the operating scenarios used to demonstrate initial compliance, documentation that affected wastewater was either discharged to a POTW or to onsite secondary treatment, and the calculation of the total organic HAP emissions from your dyeing/finishing affected source for each compliance period using Equation 4 of § 63.4331.

(d) A record of the name and mass of each regulated material applied in the web coating and printing subcategory and the dyeing and finishing subcategory during each compliance period. If you are using the compliant material option for all regulated materials at the source, you may maintain purchase records for each material used rather than a record of the mass used.

(e) A record of the mass fraction of organic HAP for each regulated material applied during each compliance period.

(f) A record of the mass fraction of coating and printing solids for each coating and printing material applied during each compliance period.

(g) If you use an allowance in Equation 1 or 4 of § 63.4331 for organic HAP contained in waste materials sent to, or designated for shipment to, a treatment, storage, and disposal facility (TSDF) according to § 63.4331(a)(4)(iii) or (b)(3)(ii), you must keep records of the information specified in paragraphs (g)(1) through (3) of this section.

(1) The name and address of each TSDF to which you sent waste materials for which you used an allowance in Equation 1 or 4 of § 63.4331, a statement of which subparts under 40 CFR parts 262, 264, 265, and 266 apply to the facility, and the date of each shipment.

(2) Identification of the web coating/printing or dyeing/finishing operations producing waste materials included in each shipment and the compliance period(s) in which you used the allowance for these materials in Equation 1 or 4, respectively, of § 63.4331.

(3) The methodology used in accordance with § 63.4331(a)(3)(iii) or (b)(4)(ii) to determine the total amount of waste materials sent to or the amount collected, stored, and designated for transport to a TSDF each compliance period; and the methodology to determine the mass of organic HAP contained in these waste materials. This must include the sources for all data used in the determination, methods used to generate the data, frequency of testing or monitoring, and supporting calculations and documentation, including the waste manifest for each shipment.

(h) If you use an allowance in Equation 4 of § 63.4331 for organic HAP contained in wastewater discharged to a POTW or treated onsite prior to

discharge according to § 63.4331(c), you must keep records of the information specified in paragraphs (h)(1) and (2) of this section.

(1) Documentation that the wastewater was either discharged to a POTW or onsite secondary wastewater treatment.

(2) Calculation of the allowance, WW, using the fraction of organic HAP applied in affected processes that is discharged to the wastewater determined from the most recent performance test and the mass of organic HAP in the dyeing and finishing materials applied during the compliance period, A, calculated in Equation 4 of § 63.4331.

(i) You must keep records of the date, time, and duration of each deviation.

(j) If you use the emission rate with add-on controls option, the organic HAP overall control efficiency option, or the oxidizer outlet organic HAP concentration option, you must keep the records specified in paragraphs (j)(1) through (8) of this section.

(1) For each deviation, a record of whether the deviation occurred during a period of startup, shutdown, or malfunction.

(2) The records in § 63.6(e)(3)(iii) through (v) related to startup, shutdown, and malfunction.

(3) The records required to show continuous compliance with each operating limit specified in Table 2 to this subpart that applies to you.

(4) For each capture system that is a PTE, the data and documentation you used to support a determination that the capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and has a capture efficiency of 100 percent, as specified in § 63.4361(a).

(5) For each capture system that is not a PTE, the data and documentation you used to determine capture efficiency according to the requirements specified in §§ 63.4360 and 63.4361(b) through (e) including the records specified in paragraphs (j)(5)(i) through (iii) of this section that apply to you.

(i) *Records for a liquid-to-fugitive protocol using a temporary total enclosure or building enclosure.* Records of the mass of total volatile hydrocarbon (TVH) as measured by Method 204A or F of appendix M to 40 CFR part 51 for each regulated material applied in the web coating/printing or dyeing/finishing operation, and the total TVH for all materials applied during each capture efficiency test run, including a copy of the test report. Records of the mass of TVH emissions not captured by the capture system that exited the temporary total enclosure or building enclosure during each capture efficiency test run, as measured by Method 204D or E of appendix M to 40 CFR part 51, including a copy of the test report. Records documenting that the enclosure used for the capture efficiency test met the criteria in Method 204 of appendix M to 40 CFR part 51 for either a temporary total enclosure or a building enclosure.

(ii) *Records for a gas-to-gas protocol using a temporary total enclosure or a building enclosure.* Records of the mass of TVH emissions captured by the emission capture system as measured by Method 204B or C of appendix M to 40 CFR part 51 at the inlet to the add-on control device, including a copy of the test report. Records of the mass of TVH emissions not captured by the capture system that exited the temporary total enclosure or building enclosure during each capture efficiency test run as measured by Method 204D or E of appendix M to 40 CFR part 51, including a copy of the test report. Records documenting that the enclosure used for the capture efficiency test met the criteria in Method 204 of appendix M to 40 CFR part 51 for either a temporary total enclosure or a building enclosure.

(iii) *Records for an alternative protocol.* Records needed to document a capture efficiency determination using an alternative method or protocol as specified in § 63.4361(e), if applicable.

(6) The records specified in paragraphs (j)(6)(i) and (ii) of this section for each add-on control device organic HAP destruction or removal efficiency determination or oxidizer outlet organic HAP concentration determination as specified in § 63.4362.

(i) Records of each add-on control device performance test conducted according to §§ 63.4360 and 63.4362.

(ii) Records of the web coating/printing or dyeing/finishing operation conditions during the add-on control device performance test showing that the performance test was conducted under representative operating conditions.

(7) Records of the data and calculations you used to establish the emission capture and add-on control device operating limits as specified in § 63.4363 and to document compliance with the operating limits as specified in Table 2 to this subpart.

(8) A record of the work practice plan required by § 63.4293 and documentation that you are implementing the plan on a continuous basis.

§ 63.4313 In what form and for how long must I keep my records?

(a) Your records must be in a form suitable and readily available for expeditious review, according to § 63.10(b)(1). Where appropriate, the records may be maintained as electronic spreadsheets or as a database.

(b) As specified in § 63.10(b)(1), you must keep each record for 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record.

(c) You must keep each record on site for at least 2 years after the date of each occurrence, measurement, maintenance, corrective action, report, or record, according to § 63.10(b)(1). You may keep the records off site for the remaining 3 years.

Compliance Requirements for the Compliant Material Option

§ 63.4320 By what date must I conduct the initial compliance demonstration?

You must complete the compliance demonstration for the initial compliance period according to the requirements in § 63.4321. The initial compliance period begins on the applicable compliance date specified in § 63.4283 and ends on the last day of the first full month after the compliance date. The initial compliance demonstration includes the calculations according to § 63.4321 and supporting documentation showing that, during the initial compliance period, the organic HAP content of each coating and printing material you applied and the mass fraction of organic HAP in each slashing, dyeing, and finishing material you applied did not exceed the applicable limit in Table 1 to this subpart, and documentation that in web coating/printing operations you applied only thinners and cleaners that contained no organic HAP as defined in § 63.4371.

§ 63.4321 How do I demonstrate initial compliance with the emission limitations?

(a) You may use the compliant material option for any individual web coating/printing operation, for any group of web coating/printing operations in the affected source, or for all the web coating/printing operations in the affected source. You must use either the emission rate without add-on controls option, the emission rate with add-on controls option, the organic HAP overall control efficiency option, or the oxidizer outlet organic HAP concentration option for any web coating/printing operation(s) in the affected source for which you do not use this option. For a web coating/printing affected source to demonstrate initial compliance using the compliant

material option, the web coating/printing operation or group of web coating/printing operations must apply no coating or printing material with an organic HAP content that exceeds the applicable emission limit in Table 1 to this subpart and must apply only thinning or cleaning material that contains no organic HAP, as defined in § 63.4371.

(b) You must use the compliant material option for each slashing affected source, as required in Table 1 to this subpart. For a slashing affected source to demonstrate initial compliance using the compliant material option, the slashing operation or group of slashing operations must apply only slashing material with no organic HAP as defined in § 63.4371.

(c) You may use the compliant material option for any individual dyeing/finishing operation, for any group of dyeing/finishing operations in the affected source, or for all the dyeing/finishing operations in the affected source. You must use either the emission rate without add-on controls option or the emission rate with add-on controls option for any dyeing/finishing operations in the affected source for which you do not use this option. You may not use the compliant material option for any dyeing/finishing operation in a dyeing/finishing affected source for which you use the equivalent emission rate option. For a dyeing/finishing affected source to demonstrate initial compliance using the compliant material option, the dyeing/finishing operation or group of dyeing/finishing operations must apply no dyeing or finishing material with a mass fraction of organic HAP that exceeds the applicable emission limit in Table 1 to this subpart.

(d) Any web coating/printing operation, slashing operation, or dyeing/finishing operation for which you use the compliant material option is not required to meet the operating limits or work practice standards required in §§ 63.4292 and 63.4293, respectively.

(e) To demonstrate initial compliance with the emission limitations using the compliant material option, you must meet all the requirements of this section for any web coating/printing operation, slashing operation, or dyeing/finishing operation using this option. Use the applicable procedures in this section on each regulated material in the condition it is in when it is received from its manufacturer or supplier and prior to any alteration. You do not need to redetermine the organic HAP content of regulated materials that are reclaimed onsite and reused in the web coating/printing operation, slashing operation, or dyeing/finishing operation for which you use the compliant material option, provided these regulated materials in their condition as received were demonstrated to comply with the compliant material option.

(1) *Determine the mass fraction of organic HAP for each material.* You must determine the mass fraction of organic HAP for each regulated material applied during the compliance period by using one of the options in paragraphs (e)(1)(i) through (v) of this section. You must use the option in paragraph (e)(1)(iv) of this section for each printing, slashing, dyeing, or finishing material applied during the compliance period.

(i) *Method 311 (appendix A to 40 CFR part 63).* You may use Method 311 for determining the mass fraction of organic HAP. Use the procedures specified in paragraphs (e)(1)(i)(A) and (B) of this section when performing a Method 311 test.

(A) Count each organic HAP that is measured to be present at 0.1 percent by mass or more for Occupational Safety and Health Administration (OSHA)-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and at 1.0 percent by mass or more for other compounds. For example, if toluene (not an OSHA carcinogen) is measured to be 0.5 percent of the material by mass, you don't have to count it. Express the mass fraction of each organic HAP you count as a value truncated to no more than four places after the decimal point (*e.g.*, 0.3791).

(B) Calculate the total mass fraction of organic HAP in the regulated material being tested by adding up the individual organic HAP mass fractions and truncating the result to no more than three places after the decimal point (*e.g.*, 0.763).

(ii) *Method 24 (appendix A to 40 CFR part 60).* You may use Method 24 to determine the mass fraction of nonaqueous volatile matter and use that value as a substitute for mass fraction of organic HAP. For a multi-component coating with reactive chemicals, you may use Method 24 on the coating as applied to determine the mass fraction of nonaqueous volatile matter and use that value as a substitute for the mass fraction of organic HAP determined from the sum of organic HAP in each component.

(iii) *Alternative method.* You may use an alternative test method for determining the mass fraction of organic HAP, mass fraction of solids, or fraction of organic HAP emitted from a reactive coating once the Administrator has approved it. You must follow the procedure in § 63.7(f) to submit an alternative test method for approval.

(iv) *Information from the supplier or manufacturer of the material.* You may rely on information other than that generated by the test methods specified in paragraphs (e)(1)(i) through (iii) of this section, such as manufacturer's formulation data, if it represents each organic HAP that is present at 0.1 percent by mass or more for OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and at 1.0 percent by mass or more for other compounds. For example, if toluene (not an OSHA carcinogen) is 0.5 percent of the material by mass, you do not have to count it. If there is a disagreement between such information and results of a test conducted according to paragraphs (e)(1)(i) through (iii) of this section on coating, thinning, or cleaning material, then the test method results will take precedence. Information from the supplier or manufacturer of the printing, slashing, dyeing, or finishing material is sufficient for determining the mass fraction of organic HAP.

(v) *Solvent blends.* Solvent blends may be listed as single components for some materials in data provided by manufacturers or suppliers. Solvent blends may contain organic HAP which must be counted toward the total organic HAP mass fraction of the materials. When test data and manufacturer's data for solvent blends are not available, you may use the default values for the mass fraction of organic HAP in these solvent blends listed in Table 4 or 5 to this subpart. If you use the tables, you must use the values in Table 4 for all solvent blends that match Table 4 entries, and you may only use Table 5 if the solvent blends in the materials you use do not match any of the solvent blends in Table 4 and you only know whether the blend is aliphatic or aromatic. However, if the results of a Method 311 test indicate higher values than those listed on Table 4 or 5 to this subpart, the Method 311 results will take precedence.

(2) *Determine the mass fraction of solids for each coating and printing material.* You must determine the mass fraction of solids (kg of solids per kg of coating or printing material) for each coating material applied during the compliance period by a test or by information provided by the supplier or the manufacturer of the material, as specified in paragraphs (e)(2)(i) through (iii) of this section. If test results obtained according to paragraph (e)(2)(i) or (ii) of this section for a coating material do not agree with the information obtained under paragraph (e)(2)(iii) of this section, the test results

will take precedence. To determine mass fraction of solids for each printing material applied during the compliance period, you should use information provided by the supplier or manufacturer of the material, as specified in paragraph (e)(2)(iii) of this section.

(i) *Method 24 (appendix A to 40 CFR part 60).* You may use Method 24 for determining the mass fraction of solids of coating materials.

(ii) *Alternative method.* You may use an alternative test method for determining solids content of each coating material once the Administrator has approved it. You must follow the procedure in § 63.7(f) to submit an alternative test method for approval.

(iii) *Information from the supplier or manufacturer of the material.* You may obtain the mass fraction of solids for each coating and printing material from the supplier or manufacturer. If there is disagreement between such information and the test method results for a coating material, then the test method results will take precedence.

(3) *Calculate the organic HAP content of each coating or printing material.* Calculate the organic HAP content, kg organic HAP per kg of solids, of each coating and printing material applied during the compliance period, using Equation 1 of this section:

$$H_c = (W_c)/(W_f) \qquad \text{(Eq. 1)}$$

Where:

H_c = Organic HAP content of the coating or printing material, kg organic HAP per kg solids in the coating or printing material.

W_c = Mass fraction of organic HAP in the coating or printing material, kg organic HAP per kg material, determined according to paragraph (e)(1) of this section.

W_f = Mass fraction of solids in coating or printing material, kg solids per kg of coating or printing material, determined according to paragraph (e)(2) of this section.

(4) *Compliance demonstration.* The calculated organic HAP content for each coating and printing material applied during the initial compliance period must be less than or equal to the applicable emission limit in Table 1 to this subpart, and each thinning and cleaning material applied during the initial compliance period must contain no organic HAP as defined in § 63.4371. Each slashing material applied during the initial compliance period must contain no organic HAP as defined in § 63.4371. The mass fraction of organic HAP for each dyeing and finishing material applied during the initial compliance period, determined according to paragraph (e)(1)(iv) of this section, must be less than or equal to the applicable emission limit in Table 1 to this subpart. You must keep all records required by §§ 63.4312 and 63.4313. As part of the Notification of Compliance Status required in § 63.4310, you must:

(i) Identify any web coating/printing operation, slashing operation, and dyeing/finishing operation for which you used the compliant material option;

(ii) Submit a statement that the web coating/printing operation(s) was (were) in compliance with the emission limitations during the initial compliance period because you applied no coating and printing material for which the organic HAP content exceeds the applicable emission limit in Table 1 to this subpart, and you applied only thinning materials and cleaning materials that contained no organic HAP, as defined in § 63.4371;

(iii) Submit a statement that the slashing operation(s) was (were) in compliance with the emission limitations during the initial compliance period because you applied only slashing materials that contained no organic HAP, as defined in § 63.4371; and

(iv) Submit a statement that the dyeing/finishing operation(s) was (were) in compliance with the emission limitations during the initial compliance period because you applied no dyeing and finishing material for which the mass fraction of organic HAP exceeds the applicable emission limit in Table 1 to this subpart.

§ 63.4322 How do I demonstrate continuous compliance with the emission limitations?

(a) For each compliance period, to demonstrate continuous compliance, you must apply no coating or printing material for which the organic HAP content determined using Equation 1 of § 63.4321, exceeds the applicable emission limit in Table 1 to this subpart. For each compliance period, to demonstrate continuous compliance, you must apply only slashing material that contains no organic HAP as defined in § 63.4371. For each compliance period, to demonstrate continuous compliance, you must apply no dyeing or finishing material for which the mass fraction of organic HAP, determined according to the requirements of § 63.4321(e)(1)(iv), exceeds the applicable emission limit in Table 1 to this subpart. For each compliance period, you must apply only thinning or cleaning materials that contain no organic HAP (as defined in § 63.4371) in a coating/printing affected source. Each month following the initial compliance period described in § 63.4320 is a compliance period.

(b) If you choose to comply with the emission limitations by using the compliant material option, the application of any regulated material that does not meet the criteria specified in paragraph (a) of this section is a deviation from the emission limitations that must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(5).

(c) As part of each semiannual compliance report required by § 63.4311, you must identify any web coating/printing operation, slashing operation, or dyeing/finishing operation for which you used the compliant material option. If there were no deviations from the applicable emission limit in Table 1 to this subpart, submit a statement that, as appropriate, the web coating/printing operations were in compliance with the emission limitations during the reporting period because you applied no coating or printing material for which the organic HAP content exceeded the applicable emission limit in Table 1 to this subpart, and you applied only thinning and cleaning materials that contained no organic HAP (as defined in § 63.4371) in a web coating/printing affected source; the slashing operations were in compliance with the emission limitations during the reporting period because you applied only slashing materials with no organic HAP (as defined in § 63.4371) in a slashing affected source; and the dyeing/finishing operations were in compliance with the emission limitations during the reporting period because you applied no dyeing or finishing material for which the mass fraction of organic HAP exceeded the applicable emission limit in Table 1 to this subpart.

(d) You must maintain records as specified in §§ 63.4312 and 63.4313.

Compliance Requirements for the Emission Rate Without Add-On Controls Option

§ 63.4330 By what date must I conduct the initial compliance demonstration?

You must complete the compliance demonstration for the initial compliance period according to the requirements of § 63.4331. The initial compliance period begins on the applicable compliance date specified in § 63.4283 and ends on the last day of the 12th full month after the compliance date. The initial compliance demonstration includes the calculations according to § 63.4331 and supporting documentation showing that for web coating/printing operations, the organic HAP emission rate for the initial

compliance period was equal to or less than the applicable emission limit in Table 1 to this subpart and for dyeing/finishing operations, the mass fraction of organic HAP for the initial compliance period was less than or equal to the applicable emission limit in Table 1 to this subpart.

§ 63.4331 How do I demonstrate initial compliance with the emission limitations?

(a) For web coating/printing operations, you may use the emission rate without add-on controls option for any individual web coating/printing operation, for any group of web coating/printing operations in the affected source, or for all the web coating/printing operations as a group in the affected source. You must use either the compliant material option, the emission rate with add-on controls option, the organic HAP overall control efficiency option, or the oxidizer outlet organic HAP concentration option for any web coating/printing operation in the affected source for which you do not use this option. To demonstrate initial compliance using the emission rate without add-on controls option, the web coating/printing operation or group of web coating/printing operations must meet the applicable emission limit in Table 1 to this subpart but is not required to meet the operating limits or work practice standards in §§ 63.4292 and 63.4293, respectively. You must meet all the requirements of paragraphs (a)(1) through (7) of this section to demonstrate initial compliance with the applicable emission limit in Table 1 to this subpart for the web coating/printing operation(s). When calculating the organic HAP emission rate according to this section, do not include any coating, printing, thinning, or cleaning materials applied on web coating/printing operations for which you use the compliant material option, the emission rate with add-on controls option, the organic HAP overall control efficiency option, or the oxidizer outlet organic HAP concentration option. Use the procedures in this section on each regulated material in the condition it is in when it is received from its manufacturer or supplier and prior to any alteration.

(1) *Determine the mass fraction of organic HAP for each material.* Determine the mass fraction of organic HAP for each coating, printing, thinning, and cleaning material applied during the compliance period according to the requirements in § 63.4321(e)(1).

(2) *Determine the mass fraction of solids for each material.* Determine the mass fraction of solids (kg of solids per kg of coating or printing material) for each coating and printing material applied during the compliance period according to the requirements in § 63.4321(e)(2).

(3) *Determine the mass of each material.* Determine the mass (kg) of each coating, printing, thinning, or cleaning material applied during the compliance period by measurement or usage records.

(4) *Calculate the mass of organic HAP emissions.* The mass of organic HAP emissions is the combined mass of organic HAP contained in all coating, printing, thinning, and cleaning materials applied during the compliance period minus the organic HAP in certain waste materials. Calculate the mass of organic HAP emissions using Equation 1 of this section:

$$H_e = A + B - R_w \qquad \text{(Eq. 1)}$$

Where:

H_e = Mass of organic HAP emissions during the compliance period, kg.

A = Total mass of organic HAP in the coating and printing materials applied during the compliance period, kg, as calculated in Equation 1A of this section.

B = Total mass of organic HAP in the thinning and cleaning materials applied during the compliance period, kg, as calculated in Equation 1B of this section.

R_w = Total mass of organic HAP in waste materials sent or designated for shipment to a hazardous waste TSDF for treatment or disposal during the compliance period, kg, determined according to paragraph (a)(4)(iii) of this section. (You may assign a value of zero to R_w if you do not wish to use this allowance.)

(i) Calculate the kg organic HAP in the coating and printing materials applied during the compliance period using Equation 1A of this section:

$$A = \sum_{i=1}^{m} \left(M_{c,i}\right)\left(W_{c,i}\right) \qquad \text{(Eq. 1A)}$$

Where:

A = Total mass of organic HAP in the coating and printing materials applied during the compliance period, kg.

$M_{c,i}$ = Total mass of coating or printing material, i, applied during the compliance period, kg.

$W_{c,i}$ = Mass fraction of organic HAP in coating or printing material, i, kg organic HAP per kg of material.

m = Number of different coating and printing, materials applied during the compliance period.

(ii) Calculate the kg of organic HAP in the thinning and cleaning materials applied during the compliance period using Equation 1B of this section:

$$B = \sum_{j=1}^{n} \left(M_{t,j}\right)\left(W_{t,j}\right) \qquad \text{(Eq. 1B)}$$

Where:

B = Total mass of organic HAP in the thinning and cleaning materials applied during the compliance period, kg.

$M_{t,j}$ = Total mass of thinning or cleaning material, j, applied during the compliance period, kg.

$W_{t,j}$ = Mass fraction of organic HAP in thinning or cleaning material, j, kg organic HAP per kg thinning or cleaning material.

n = Number of different thinning and cleaning materials applied during the compliance period.

(iii) If you choose to account for the mass of organic HAP contained in waste materials sent or designated for shipment to a hazardous waste TSDF in Equation 1 of this section, then you must determine it according to paragraphs (a)(4)(iii)(A) through (D) of this section.

(A) You may include in the determination only waste materials that are generated by web coating/printing operations in the affected source for which you use Equation 1 of this section and that will be treated or disposed of by a facility that is regulated as a TSDF under 40 CFR part 262, 264, 265, or 266. The TSDF may be either off-site or on-site. You may not include organic HAP contained in wastewater.

(B) You must determine either the amount of the waste materials sent to a TSDF during the compliance period or the amount collected and stored during the compliance period designated for future transport to a TSDF. Do not include in your determination any waste materials sent to a TSDF during a compliance period if you have already included them in the amount collected and stored during that compliance period or a previous compliance period.

(C) Determine the total mass of organic HAP contained in the waste materials specified in paragraph (a)(4)(iii)(B) of this section.

(D) You must document the methodology you use to determine the amount of waste materials and the total mass of organic HAP they contain, as required in § 63.4312(g). To the extent that waste manifests include this, they may be used as part of the documentation of the amount of waste materials and mass of organic HAP contained in them.

(5) *Calculate the total mass of coating and printing solids.* Determine the total

mass of coating and printing solids applied, kg, which is the combined mass of the solids contained in all the coating and printing materials applied during the compliance period, using Equation 2 of this section:

$$H_t = \sum_{i=1}^{m} \left(M_{c,i}\right)\left(W_{f,i}\right) \qquad \text{(Eq. 2)}$$

Where:

H_t = Total mass of solids contained in coating and printing materials applied during the compliance period, kg.

$M_{c,i}$ = Mass of coating or printing material, i, applied during the compliance period, kg.

$W_{f,i}$ = mass fraction of solids in coating or printing material, i, applied during the compliance period, kg solids per kg of coating or printing material.

m = Number of coating and printing materials applied during the compliance period.

(6) Calculate the organic HAP emission rate for the compliance period, kg organic HAP emitted per kg solids used, using Equation 3 of this section:

$$H_{yr} = \frac{H_e}{H_t} \qquad \text{(Eq. 3)}$$

Where:

H_{yr} = Organic HAP emission rate for the compliance period, kg of organic HAP emitted per kg of solids in coating and printing materials applied.

H_e = Total mass organic HAP emissions from all coating, printing, thinning, and cleaning materials applied during the compliance period, kg, as calculated by Equation 1 of this section.

H_t = Total mass of coating and printing solids in materials applied during the compliance period, kg, as calculated by Equation 2 of this section.

(7) *Compliance demonstration.* The organic HAP emission rate for the initial compliance period must be less than or equal to the applicable emission limit in Table 1 to this subpart. You must keep all records as required by §§ 63.4312 and 63.4313. As part of the Notification of Compliance Status required by § 63.4310, you must identify the web coating/printing operation(s) for which you used the emission rate without add-on controls option and submit a statement that the web coating/printing operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP emission rate was less than, or equal to, the applicable emission limit in Table 1 to this subpart.

(b) For dyeing and finishing operations, you may use the emission rate without add-on controls option for any individual dyeing/finishing operation, for any group of dyeing/finishing operations in the affected source, or for dyeing/finishing operations as a group in the affected source. You must use either the compliant material option or the emission rate with add-on controls option for any dyeing/finishing operation in the affected source for which you do not use this option. You may not use the emission rate without add-on controls option for any dyeing/finishing operation in a dyeing/finishing affected source for which you use the equivalent emission rate option. To demonstrate initial compliance using the emission rate without add-on controls option, the dyeing/finishing operation or group of operations must meet the applicable emission limit in Table 1 to this subpart but is not required to meet the operating limits or work practice standards in §§ 63.4292 and 63.4293, respectively. You must meet all the requirements of paragraphs (b)(1) through (6) of this section to demonstrate initial compliance with the applicable emission limit in Table 1 to this subpart for the dyeing/finishing operation(s). When calculating the organic HAP emission rate according to this section, do not include any dyeing and finishing materials applied on dyeing/finishing operations for which you use the compliant material option or the emission rate with add-on controls option. Use the procedures in this section on each regulated material in the condition it is in when it is received from its manufacturer or supplier and prior to any alteration. Water added in mixing at the affected source is not a regulated material and should not be included in the determination of the total mass of dyeing and finishing materials applied during the compliance period, using Equation 5 of this section.

(1) *Determine the mass fraction of organic HAP for each material.* Determine the mass fraction of organic HAP for each dyeing and finishing material applied during the compliance period according to the requirements in § 63.4321(e)(1)(iv).

(2) *Determine the mass of each material.* Determine the mass (kg) of each dyeing and finishing material applied during the compliance period by measurement or usage records.

(3) *Calculate the mass of organic HAP emissions.* The mass of organic HAP emissions is the combined mass of organic HAP contained in all dyeing and finishing materials applied during the compliance period minus the organic HAP in certain waste materials and wastewater streams. Calculate the mass of organic HAP emissions using Equation 4 of this section:

$$H_e = A - R_w - WW \qquad \text{(Eq. 4)}$$

Where:

H_e = Mass of organic HAP emissions during the compliance period, kg.

A = Total mass of organic HAP in the dyeing and finishing materials applied during the compliance period, kg, as calculated in Equation 4A of this section.

R_w = Total mass of organic HAP in waste materials sent or designated for shipment to a hazardous waste TSDF for treatment or disposal during the compliance period, kg, determined according to paragraph (b)(3)(ii) of this section. (You may assign a value of zero to R_w if you do not wish to use this allowance.)

WW = Total mass of organic HAP in wastewater discharged to a POTW or receiving onsite secondary treatment during the compliance period, kg, determined according to paragraph (b)(3)(iii) of this section. (You may assign a value of zero to WW if you do not wish to use this allowance.)

(i) Calculate the kg organic HAP in the dyeing and finishing materials applied during the compliance period using Equation 4A of this section:

$$A = \sum_{i=1}^{m} \left(M_{c,i}\right)\left(W_{c,i}\right) \qquad \text{(Eq. 4A)}$$

Where:

A = Total mass of organic HAP in the dyeing and finishing materials applied during the compliance period, kg.

$M_{c,i}$ = Mass of dyeing or finishing material, i, applied during the compliance period, kg.

$W_{c,i}$ = Mass fraction of organic HAP in dyeing or finishing material, i, kg organic HAP per kg of material.

m = Number of dyeing and finishing materials applied during the compliance period.

(ii) If you choose to account for the mass of organic HAP contained in waste materials sent or designated for shipment to a hazardous waste TSDF in Equation 4 of this section, then you must determine it according to paragraphs (b)(3)(ii)(A) through (D) of this section.

(A) You may include in the determination only waste materials that are generated by dyeing/finishing

operations in the affected source for which you use Equation 4 of this section and that will be treated or disposed of by a facility that is regulated as a TSDF under 40 CFR part 262, 264, 265, or 266. The TSDF may be either off-site or on-site. You may not include organic HAP contained in wastewater.

(B) You must determine either the amount of the waste materials sent to a TSDF during the compliance period or the amount collected and stored during the compliance period designated for future transport to a TSDF. Do not include in your determination any waste materials sent to a TSDF during a compliance period if you have already included them in the amount collected and stored during that compliance period or a previous compliance period.

(C) Determine the total mass of organic HAP contained in the waste materials specified in paragraph (b)(3)(ii)(B) of this section.

(D) You must document the methodology you use to determine the amount of waste materials and the total mass of organic HAP they contain, as required in § 63.4312(g). To the extent that waste manifests include this, they may be used as part of the documentation of the amount of waste materials and mass of organic HAP contained in them.

(iii) If you choose to account for the mass of organic HAP contained in wastewater discharged to a POTW or treated onsite prior to discharge in Equation 4 of this section, then you must determine it according to paragraph (c) of this section.

(4) *Calculate the total mass of dyeing and finishing materials.* Determine the total mass of dyeing and finishing materials applied, kg, which is the combined mass of all the dyeing and finishing materials applied during the compliance period, using Equation 5 of this section:

$$M_t = \sum_{i=1}^{m} \left(M_{c,i} \right) \qquad \text{(Eq. 5)}$$

Where:

M_t = Total mass of dyeing and finishing materials applied during the compliance period, kg.

$M_{c,i}$ = Mass of dyeing or finishing material, i, applied during the compliance period, kg.

m = Number of dyeing and finishing materials applied during the compliance period.

(5) Calculate the organic HAP emission rate, kg organic HAP emitted per kg dyeing and finishing material applied, using Equation 6 of this section:

$$H_{yr} = \frac{H_e}{M_t} \qquad \text{(Eq. 6)}$$

Where:

H_{yr} = The organic HAP emission rate for the compliance period, kg of organic HAP emitted per kg of dyeing and finishing materials.

H_e = Total mass of organic HAP emissions during the compliance period, kg, as calculated by Equation 4 of this section.

M_t = Total mass of dyeing and finishing materials applied during the compliance period, kg, as calculated by Equation 5 of this section.

(6) *Compliance demonstration.* The organic HAP emission rate for the initial compliance period must be less than or equal to the applicable emission limit in Table 1 to this subpart. You must keep all records as required by §§ 63.4312 and 63.4313. As part of the Notification of Compliance Status required by § 63.4310, you must identify the dyeing/finishing operation(s) for which you used the emission rate without add-on controls option and submit a statement that the dyeing/finishing operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP emission rate was less than or equal to the applicable emission limit in Table 1 to this subpart.

(i) If your affected source performs only dyeing operations, paragraphs (b)(1) through (5) of this section apply to dyeing materials only, and you must demonstrate compliance with the emission limit in Table 1 to this subpart for dyeing operations.

(ii) If your affected source performs only finishing operations, paragraphs (b)(1) through (5) of this section apply to finishing materials only, and you must demonstrate compliance with the emission limit in Table 1 to this subpart for finishing operations.

(iii) If your affected source performs both dyeing and finishing operations, paragraphs (b)(1) through (5) of this section apply to dyeing and finishing materials combined, and you must demonstrate compliance with the emission limit in Table 1 to this subpart for dyeing and finishing operations.

(c) If you choose to account for the mass of organic HAP contained in wastewater discharged to a POTW or treated onsite prior to discharge in Equation 4 of this section, then you must determine it according to paragraphs (c)(1) through (5) of this section. You may include in the determination only wastewater streams that are generated by dyeing/finishing operations in the affected source for which you use Equation 4 of this section. You must determine the mass of organic HAP from the average organic HAP concentration and mass flow rate of each wastewater stream generated by the affected dyeing/finishing operation (or group of dyeing/finishing operations discharging to a common wastewater stream) for which you use this allowance. You must consider the actual or anticipated production over the compliance period and include all wastewater streams generated by the affected dyeing/finishing operation(s) during this period. A performance test of the organic HAP loading to the wastewater shall be performed for each operating scenario, as defined in § 63.4371, during the compliance period.

(1) *Procedure to determine average organic HAP concentration.* You must determine the average organic HAP concentration, H_w, of each wastewater stream according to paragraphs (c)(1)(i) through (vi) of this section.

(i) *Sampling.* Wastewater samples may be grab samples or composite samples. Samples shall be taken at approximately equally spaced time intervals over a 1-hour period (or over the period that wastewater is being discharged from a batch process if it is shorter than a 1-hour period). Each 1-hour period constitutes a run, and a performance test shall consist of a minimum of 3 runs.

(ii) *Methods.* You may use any of the methods specified in paragraphs (c)(1)(ii)(A) through (E) of this section to determine the organic HAP content of the wastewater stream. The method shall be an analytical method for wastewater which has the organic HAP compound discharged to the wastewater as a target analyte.

(A) *Method 305.* Use procedures specified in Method 305 of 40 CFR part 63, appendix A.

(B) *Methods 624 and 625.* Use procedures specified in Method 624 and Method 625 of 40 CFR part 136, appendix A and comply with the sampling protocol requirements specified in paragraph (c)(1)(iii) of this section. If these methods are used to analyze one or more compounds that are not on the method's published list of approved compounds, the Alternative Test Procedure specified in 40 CFR 136.4 and 136.5 shall be followed. For Method 625, make corrections to the compounds for which the analysis is being conducted based on the accuracy as recovery factors in Table 7 of the method.

(C) *Methods 1624 and 1625.* Use procedures specified in Method 1624

and Method 1625 of 40 CFR part 136, appendix A and comply with the sampling protocol requirements specified in paragraph (c)(1)(iii) of this section. If these methods are used to analyze one or more compounds that are not on the method's published list of approved compounds, the Alternative Test Procedure specified in 40 CFR 136.4 and 136.5 shall be followed.

(D) *Other EPA method(s).* Use procedures specified in the method and comply with the requirements specified in paragraphs (c)(1)(iii) and either paragraph (c)(1)(iv)(A) or (B) of this section.

(E) *Methods other than EPA method.* Use procedures specified in the method and comply with the requirements specified in paragraphs (c)(1)(iii) and paragraph (c)(1)(iv)(A) of this section.

(iii) *Sampling plan.* If you have been expressly referred to this paragraph by provisions of this subpart, you shall prepare a sampling plan. Wastewater samples shall be collected using sampling procedures which minimize loss of organic compounds during sample collection and analysis and maintain sample integrity. The sampling plan shall include procedures for determining recovery efficiency of the relevant organic HAP. An example of an example sampling plan would be one that incorporates similar sampling and sample handling requirements to those of Method 25D of 40 CFR part 60, appendix A. You shall maintain the sampling plan at the facility.

(iv) *Validation of methods.* You shall validate EPA methods other than Methods 305, 624, 625, 1624, 1625 using the procedures specified in paragraph (c)(1)(iv)(A) or (B) of this section.

(A) *Validation of EPA methods and other methods.* The method used to measure organic HAP concentrations in the wastewater shall be validated according to section 5.1 or 5.3, and the corresponding calculations in section 6.1 or 6.3, of Method 301 of appendix A of this part. The data are acceptable if they meet the criteria specified in section 6.1.5 or 6.3.3 of Method 301 of appendix A of this part. If correction is required under section 6.3.3 of Method 301 of appendix A of this part, the data are acceptable if the correction factor is within the range 0.7 to 1.30. Other sections of Method 301 of appendix A of this part are not required.

(B) *Validation for EPA methods.* Follow the procedures as specified in ''Alternative Validation Procedure for EPA Waste Methods'' 40 CFR part 63, appendix D.

(v) *Calculate the average concentration.* You shall calculate the average concentration for each individually speciated organic HAP compound by adding the individual values determined for the specific compound in each sample and dividing by the number of samples.

(vi) *Adjustment for concentrations determined downstream of the point of determination.* You shall make corrections to the specific compound average concentration or total organic HAP average concentration when the concentration is determined downstream of the point of determination at a location where either wastewater streams from outside of the affected dyeing/finishing operation or group of dyeing/finishing operations have been mixed with the affected wastewater stream or one or more affected wastewater streams have been treated. You shall make the adjustments either to the individual data points or to the final average organic HAP concentration.

(2) *Procedures to determine mass flow rate.* For each operating scenario, as defined in § 63.4371, for which you have determined the organic HAP content of the wastewater stream, you shall determine the annual average mass flow rate, F_w, of the wastewater stream either at the point of determination or downstream of the point of determination with adjustment for flow rate changes made according to paragraph (c)(2)(ii) of this section. The annual average mass flow rate for the wastewater stream shall be representative of actual or anticipated operation of the dyeing/finishing operation(s) generating the wastewater over the compliance period. You must determine the annual average mass flow rate of each wastewater stream according to paragraphs (c)(2)(i) and (ii) of this section.

(i) *Procedures.* The procedures specified in paragraphs (c)(2)(i)(A) through (C) of this section are considered acceptable procedures for determining the mass flow rate. They may be used in combination, and no one procedure shall take precedence over another.

(A) *Knowledge of the wastewater.* You may use knowledge of the wastewater stream and/or the process to determine the annual average mass flow rate. You shall use the maximum expected annual average production capacity of the dyeing/finishing operation(s), knowledge of the process, and/or mass balance information to either estimate directly the average wastewater mass flow rate for the compliance period or estimate the total wastewater mass flow for the compliance period and then factor the total mass by the percentage of time in the compliance period the operating scenario is expected to represent. Where you use knowledge to determine the annual average mass flow rate, you shall provide sufficient information to document the mass flow rate.

(B) *Historical records.* You may use historical records to determine the average annual mass flow rate. Derive the highest annual average mass flow rate of wastewater from historical records representing the most recent 5 years of operation, or if the dyeing/finishing operation(s) has(have) been in service for less than 5 years but at least 1 year, from historical records representing the total operating life of the process unit. Where historical records are used to determine the annual average mass flow rate, you shall provide sufficient information to document the mass flow rate.

(C) *Measurement of mass flow rate.* If you elect to measure mass flow rate, you shall comply with the requirements of this paragraph. Measurements shall be made at the point of determination, or at a location downstream of the point of determination with adjustments for mass flow rate changes made according to paragraph (c)(2)(ii) of this section. Where measurement data are used to determine the annual average mass flow rate, you shall provide sufficient information to document the mass flow rate.

(ii) *Adjustment for flow rates determined downstream of the point of determination.* You shall make corrections to the average annual mass flow rate of a wastewater stream when it is determined downstream of the point of determination at a location where either wastewater streams from outside of the affected dyeing/finishing operation or group of dyeing/finishing operations have been mixed with the affected wastewater stream or one or more wastewater streams have been treated. You shall make corrections for such changes in the annual average mass flow rate.

(3) *Wastewater treatment.* You shall document that the wastewater is either discharged to a POTW or onsite secondary wastewater treatment.

(4) *Determine the mass of organic HAP in the affected wastewater.* Determine the total mass of organic HAP, WW, contained in the wastewater streams characterized by the procedures in paragraphs (c)(1) and (2) of this section, using Equation 7 of this section:

$$WW = \sum_{k=1}^{o} \left(H_{w,k}\right)\left(F_{w,k}\right) \times 10^{-3} \qquad \text{(Eq. 7)}$$

Where:

WW = The total mass of organic HAP contained in the wastewater streams characterized by the procedures in paragraphs (c)(1) and (2) of this section, kg/yr

$H_{w,k}$ = Average organic HAP concentration of wastewater stream k, ppmw

$F_{w,k}$ = Annual average mass flow rate of wastewater stream k, Mg/yr

o = Number of wastewater streams characterized by the procedures in paragraphs (c)(1) and (2) of this section.

This is your allowance for organic HAP discharged to wastewater and not emitted to the atmosphere, WW in Equation 4.

(5) *Determine the fraction of organic HAP applied that is discharged to the wastewater.* For the purpose of taking credit for the wastewater allowance in continuous compliance demonstrations, determine the fraction of organic HAP applied in affected dyeing/finishing processes that is discharged to the wastewater, *i.e.*, divide WW by the mass of organic HAP in the dyeing and finishing materials applied during the compliance period, A, as calculated in Equation 4A of this section. The wastewater allowance for this fraction of organic HAP that is not emitted from the affected dyeing/finishing operation(s) may be taken for each compliance period that the operating scenario, as defined in § 63.4371, does not change from conditions during the performance test in a way that could increase the fraction of organic HAP emitted (*e.g.*, an increase in process temperature or decrease in process pressure or a change in the type or mass fraction of organic HAP entering the dyeing/finishing operation.) The allowance, WW, must be calculated by multiplying the fraction of organic HAP applied in affected processes that is discharged to the wastewater determined from the most recent performance test by the mass of organic HAP in the dyeing and finishing materials applied during the compliance period, A, as calculated in Equation 4A of this section.

(d) If you are determining the fraction of organic HAP applied in your dyeing/finishing affected source that is discharged to the wastewater, to demonstrate compliance with the equivalent emission rate option of § 63.4291(c)(4), then you must determine it according to paragraphs (d)(1) through (5) of this section. You must include in the determination only wastewater streams generated by dyeing/finishing operations in your affected source. You shall determine the mass of organic HAP from the average organic HAP concentration and mass flow rate of each wastewater stream generated by each dyeing/finishing operation (or group of dyeing/finishing operations discharging to a common wastewater stream) in your affected source. You shall consider the actual or anticipated production over the compliance period and include all wastewater streams generated by the affected dyeing/finishing operation(s) during this period. A performance test of the organic HAP loading to the wastewater shall be conducted for each operating scenario, as defined in § 63.4371, during the compliance period.

(1) *Procedure to determine average organic HAP concentration.* You must determine the average organic HAP concentration of each wastewater stream according to paragraphs (c)(1)(i) through (vi) of this section.

(2) *Procedures to determine mass flow rate.* For each operating scenario, as defined in § 63.4371, for which you have determined the organic HAP content of the wastewater stream, you shall determine the annual average mass flow rate of the wastewater stream either at the point of determination, or downstream of the point of determination with adjustment for flow rate changes made according to paragraph (c)(2)(ii) of this section. The annual average mass flow rate for the wastewater stream shall be representative of actual or anticipated operation of the dyeing/finishing operation(s) generating the wastewater over the compliance period. You must determine the annual average mass flow rate of each wastewater stream according to paragraphs (c)(2)(i) and (ii) of this section.

(3) *Wastewater treatment.* You shall document that the wastewater is either discharged to a POTW or onsite secondary wastewater treatment.

(4) *Determine the mass of organic HAP in the affected wastewater.* Determine the total mass of organic HAP, WW, contained in the wastewater streams characterized by the procedures in paragraphs (d)(1) and (2) of this section, using Equation 7 of this section.

(5) *Determine the fraction of organic HAP applied that is discharged to the wastewater.* Determine the fraction of organic HAP applied in your dyeing/finishing affected source that is discharged to the wastewater, *i.e.*, divide WW by the mass of organic HAP in the dyeing and finishing materials applied during the compliance period, A, as calculated in Equation 4A of this section. One of the conditions that must be met to demonstrate compliance with the equivalent emission rate option is that the fraction of organic HAP applied in your dyeing/finishing affected source that is discharged to the wastewater must be at least 90 percent.

§ 63.4332 How do I demonstrate continuous compliance with the emission limitations?

(a) To demonstrate continuous compliance, the organic HAP emission rate for each compliance period, determined according to § 63.4331(a) for web coating/printing operations and according to § 63.4331(b) for dyeing/finishing operations, must be less than or equal to the applicable emission limit in Table 1 to this subpart. Each month following the initial compliance period described in § 63.4330 is a compliance period consisting of that month and the preceding 11 months. You must perform the calculations in § 63.4331 on a monthly basis.

(b) If the organic HAP emission rate for any compliance period exceeded the applicable emission limit in Table 1 to this subpart, this is a deviation from the emission limitations for that compliance period and must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(6).

(c) As part of each semiannual compliance report required by § 63.4311, you must identify any web coating/printing operation or dyeing/finishing operation for which you used the emission rate without add-on controls option. If there were no deviations from the applicable emission limit in Table 1 to this subpart, you must submit a statement that, as appropriate, the web coating/printing operations or the dyeing/finishing operations were in compliance with the emission limitations during the reporting period because the organic HAP emission rate for each compliance period was less than or equal to the applicable emission limit in Table 1 to this subpart.

(d) You must maintain records as specified in §§ 63.4312 and 63.4313.

Compliance Requirements for the Emission Rate With Add-On Controls Option

§ 63.4340 By what date must I conduct performance tests and other initial compliance demonstrations?

(a) *New and reconstructed affected sources.* For a new or reconstructed affected source, you must meet the requirements of paragraphs (a)(1) through (4) of this section.

(1) All emission capture systems, add-on control devices, and CPMS must be installed and operating no later than the applicable compliance date specified in § 63.4283. Except for solvent recovery

systems for which you conduct liquid-liquid material balances according to § 63.4341(e)(5) or (f)(5), you must conduct a performance test of each capture system and add-on control device according to the procedures in §§ 63.4360, 63.4361, and 63.4362, and establish the operating limits required by § 63.4292, within 180 days of the applicable compliance date specified in § 63.4283. For a solvent recovery system for which you conduct liquid-liquid material balances according to § 63.4341(e)(5) or (f)(5), you must initiate the first material balance no later than the applicable compliance date specified in § 63.4283.

(2) You must develop and begin implementing the work practice plan required by § 63.4293 no later than the compliance date specified in § 63.4283.

(3) You must complete the compliance demonstration for the initial compliance period according to the requirements of § 63.4341. The initial compliance period begins on the applicable compliance date specified in § 63.4283 and ends on the last day of the 12th full month after the compliance date, or the date you conduct the performance tests of the emission capture systems and add-on control devices, or initiate the first liquid-liquid material balance for a solvent recovery system, whichever is later. The initial compliance demonstration includes the results of emission capture system and add-on control device performance tests conducted according to §§ 63.4360, 63.4361, and 63.4362; results of liquid-liquid material balances conducted according to § 63.4341(e)(5) or (f)(5); calculations according to § 63.4341 and supporting documentation showing that during the initial compliance period the organic HAP emission rate was equal to or less than the applicable emission limit in Table 1 to this subpart; the operating limits established during the performance tests and the results of the continuous parameter monitoring required by § 63.4364; and documentation of whether you developed and implemented the work practice plan required by § 63.4293.

(4) You do not need to comply with the operating limits for the emission capture system and add-on control device required by § 63.4292 until after you have completed the performance tests specified in paragraph (a)(1) of this section. Instead, you must maintain a log detailing the operation and maintenance of the emission capture system, add-on control device, and continuous parameter monitors during the period between the compliance date and the performance test. You must begin complying with the operating limits for your affected source on the date you complete the performance tests specified in paragraph (a)(1) of this section. This requirement does not apply to solvent recovery systems for which you conduct liquid-liquid material balances according to the requirements of § 63.4341(e)(5) or (f)(5).

(b) *Existing sources.* For an existing affected source, you must meet the requirements of paragraphs (b)(1) through (3) of this section.

(1) All emission capture systems, add-on control devices, and CPMS must be installed and operating no later than the applicable compliance date specified in § 63.4283. Except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4341(e)(5) or (f)(5), you must conduct a performance test of each capture system and add-on control device according to the procedures in §§ 63.4360, 63.4361, and 63.4362, and establish the operating limits required by § 63.4292, within 180 days of the compliance date specified in § 63.4283. For a solvent recovery system for which you conduct liquid-liquid material balances according to § 63.4341(e)(5) or (f)(5), you must initiate the first material balance no later than the compliance date specified in § 63.4283.

(2) You must develop and begin implementing the work practice plan required by § 63.4293 no later than the compliance date specified in § 63.4283.

(3) You must complete the compliance demonstration for the initial compliance period according to the requirements of § 63.4341. The initial compliance period begins on the applicable compliance date specified in § 63.4283 and ends on the last day of the 12th full month after the compliance date. The initial compliance demonstration includes the results of emission capture system and add-on control device performance tests conducted according to §§ 63.4360, 63.4361, and 63.4362; results of liquid-liquid material balances conducted according to § 63.4341(e)(5) or (f)(5); calculations according to § 63.4561 and supporting documentation showing that during the initial compliance period the organic HAP emission rate was equal to or less than the applicable emission limit in Table 1 to this subpart; the operating limits established during the performance tests and the results of the continuous parameter monitoring required by § 63.4364; and documentation of whether you developed and implemented the work practice plan required by § 63.4293.

§ 63.4341 How do I demonstrate initial compliance?

(a) You may use the emission rate with add-on controls option for any individual web coating/printing operation, for any group of web coating/printing operations in the affected source, or for all of the web coating/printing operations in the affected source. You may include both controlled and uncontrolled web coating/printing operations in a group for which you use this option. You must use either the compliant material option, the emission rate without add-on controls option, the organic HAP overall control efficiency option, or the oxidizer outlet organic HAP concentration option for any web coating/printing operation in the affected source for which you do not use the emission rate with add-on controls option. To demonstrate initial compliance, any web coating/printing operation for which you use the emission rate with add-on controls option must meet the applicable emission limitations in Table 1 to this subpart, and in §§ 63.4292 and 63.4293. You must meet all the requirements of paragraphs (a), (c), (d), and (e) of this section. When calculating the organic HAP emission rate according to this section, do not include any coating, printing, thinning, or cleaning materials applied on web coating/printing operations for which you use the compliant material option, the emission rate without add-on controls option, the organic HAP overall control efficiency option, or the oxidizer outlet organic HAP concentration option. You do not need to redetermine the mass of organic HAP in coating, printing, thinning, or cleaning materials that have been reclaimed onsite and reused in the web coating/printing operation(s) for which you use the emission rate with add-on control option.

(b) You may use the emission rate with add-on controls option for any individual dyeing/finishing operation, for any group of dyeing/finishing operations in the affected source, or for all of the dyeing/finishing operations in the affected source. You may include both controlled and uncontrolled dyeing/finishing operations in a group for which you use this option. You must use either the compliant material option or the emission rate without add-on controls option for any dyeing/finishing operation in the affected source for which you do not use the emission rate with add-on controls option. You may not use the emission rate with add-on controls option for any dyeing/finishing operation in a dyeing/finishing affected source for which you use the equivalent

emission rate option. To demonstrate initial compliance, any dyeing/finishing operation for which you use the emission rate with add-on controls option must meet the applicable emission limitations in Table 1 to this subpart, and in §§ 63.4292 and 63.4293. You must meet all the requirements of paragraphs (b), (c), (d), and (f) this section. When calculating the organic HAP emission rate according to this section, do not include any dyeing or finishing materials applied on dyeing/finishing operations for which you use the compliant material option or the emission rate without add-on controls option. You do not need to redetermine the mass of organic HAP in dyeing or finishing materials that have been reclaimed onsite and reused in the dyeing/finishing operation(s) for which you use the emission rate with add-on controls option.

(c) *Compliance with operating limits.* Except as provided in § 63.4340(a)(4), and except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4341(e)(5) or (f)(5), you must establish and demonstrate continuous compliance during the initial compliance period with the operating limits required by § 63.4292, using the procedures specified in §§ 63.4363 and 63.4364.

(d) *Compliance with work practice requirements.* You must develop, implement, and document your implementation of the work practice plan required by § 63.4293 during the initial compliance period as specified in § 63.4312.

(e) *Compliance with web coating/printing emission limits.* You must follow the procedures in paragraphs (e)(1) through (8) of this section to demonstrate compliance with the applicable web coating/printing emission limit in Table 1 to this subpart.

(1) *Determine the mass fraction of organic HAP, the mass fraction of solids, and mass of materials.* Follow the procedures specified in § 63.4331(a)(1), (2), and (3) to determine the mass fraction of organic HAP for each coating, printing, thinning, and cleaning material applied during the compliance period; the mass fraction of solids for each coating and printing material applied during the compliance period; and mass of each coating, printing, thinning, and cleaning material applied during the compliance period.

(2) *Calculate the mass of organic HAP emissions before add-on controls.* Using Equation 1 of § 63.4331, calculate the mass of organic HAP emissions before add-on controls from all coating, printing, thinning, and cleaning materials applied during the compliance period minus the organic HAP in certain waste materials in the web coating/printing operation or group of web coating/printing operations for which you use the emission rate with add-on controls.

(3) *Calculate the organic HAP emissions reductions for each controlled web coating/printing operation.* Determine the mass of organic HAP emissions reduced for each controlled web coating/printing operation during the compliance period. The emissions reductions determination quantifies the total organic HAP emissions that pass through the emission capture system and are destroyed or removed by the add-on control device. Use the procedures in paragraph (e)(4) of this section to calculate the mass of organic HAP emissions reductions for each controlled web coating/printing operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances. For each controlled web coating/printing operation using a solvent recovery system for which you conduct a liquid-liquid material balance, use the procedures in paragraph (e)(5) of this section to calculate the organic HAP emissions reductions.

(4) *Calculate the organic HAP emission reduction for each controlled web coating/printing operation not using liquid-liquid material balance.* For each controlled web coating/printing operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances, calculate the organic HAP emissions reductions using Equation 1 of this section. The equation applies the emission capture system efficiency and add-on control device efficiency to the mass of organic HAP contained in the coating, printing, thinning, and cleaning materials applied in the web coating/printing operation served by the emission capture system and add-on control device during the compliance period. For any period of time a deviation specified in § 63.4342(c) or (d) occurs in the controlled web coating/printing operation, including a deviation during startup, shutdown, or malfunction, then you must assume zero efficiency for the emission capture system and add-on control device. Equation 1 of this section treats the coating, printing, thinning, and cleaning materials applied during such a deviation as if they were used on an uncontrolled web coating/printing operation for the time period of the deviation.

$$H_C = \left(A_I + B_I - H_{UNC}\right)\left(\frac{CE}{100} \times \frac{DRE}{100}\right) \qquad \text{(Eq. 1)}$$

Where:

H_C = Mass of organic HAP emission reduction for the controlled web coating/printing operation during the compliance period, kg.

A_I = Total mass of organic HAP in the coating and printing materials applied in the controlled web coating/printing operation during the compliance period, kg, as calculated in Equation 1A of this section.

B_I = Total mass of organic HAP in the thinning and cleaning materials applied in the controlled web coating/printing operation during the compliance period, kg, as calculated in Equation 1B of this section.

H_{UNC} = Total mass of organic HAP in the coating, printing, thinning, and cleaning materials applied during all deviations specified in § 63.4342(c) and (d) that occurred during the compliance period in the controlled web coating/printing operation, kg, as calculated in Equation 1C of this section.

CE = Capture efficiency of the emission capture system vented to the add-on control device, percent. Use the test methods and procedures specified in §§ 63.4360 and 63.4361 to measure and record capture efficiency.

DRE = Organic HAP destruction or removal efficiency of the add-on control device, percent. Use the test methods and procedures in §§ 63.4360 and 63.4362 to measure and record the organic HAP destruction or removal efficiency.

(i) Calculate the total mass of organic HAP in the coating and printing materials applied in the controlled web

coating/printing operation(s) during the compliance period, kg, using Equation 1A of this section:

$$A_I = \sum_{i=1}^{m} \left(M_{c,i}\right)\left(W_{c,i}\right) \qquad \text{(Eq. 1A)}$$

Where:

A_I = Total mass of organic HAP in the coating and printing materials applied in the controlled web coating/printing operation(s) during the compliance period, kg.

$M_{c,i}$ = Mass of coating or printing material, i, applied during the compliance period, kg.

$W_{c,i}$ = Mass fraction of organic HAP in coating or printing material, i, kg per kg.

m = Number of different coating and printing materials applied during compliance period.

(ii) Calculate the total mass of organic HAP in the thinning and cleaning materials applied in the controlled web coating/printing operation(s) during the compliance period, kg, using Equation 1B of this section:

$$B_I = \sum_{j=1}^{n} \left(M_{t,j}\right)\left(W_{t,j}\right) \qquad \text{(Eq. 1B)}$$

Where:

B_I = Total mass of organic HAP in the thinning and cleaning materials applied in the controlled web coating/printing operation(s) during the compliance period, kg.

$M_{t,j}$ = Total mass of thinning or cleaning material, j, applied during the compliance period, kg.

$W_{t,j}$ = Mass fraction of organic HAP in thinning or cleaning material, j, kg per kg.

n = Number of different thinning and cleaning materials applied during the compliance period.

(iii) Calculate the mass of organic HAP in the coating, printing, thinning, and cleaning materials applied in the controlled web coating/printing operation during deviations specified in § 63.4342(c) and (d), using Equation 1C of this section.

$$H_{UNC} = \sum_{h=1}^{q} \left(M_h\right)\left(W_h\right) \qquad \text{(Eq. 1C)}$$

Where:

H_{UNC} = Total mass of organic HAP in the coating, printing, thinning, and cleaning materials applied during all deviations specified in § 63.4342 (c) and (d) that occurred during the compliance period in the controlled web coating/printing operation, kg.

M_h = Total mass of coating, printing, thinning, or cleaning material, h, applied in the controlled web coating/printing operation during deviations, kg.

W_h = Mass fraction of organic HAP in coating, printing, thinning, or cleaning material, h, kg organic HAP per kg material.

q = Number of different coating, printing, thinning, and cleaning materials applied and used.

(5) *Calculate the organic HAP emissions reductions for controlled web coating/printing operation using liquid-liquid material balances.* For each controlled web coating/printing operation using a solvent recovery system for which you conduct liquid-liquid material balances, calculate the organic HAP emissions reductions by applying the volatile organic matter collection and recovery efficiency to the mass of organic HAP contained in the coating, printing, thinning, and cleaning materials applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period. Perform a liquid-liquid material balance for the compliance period as specified in paragraphs (e)(5)(i) through (v) of this section. Calculate the mass of organic HAP emissions reductions by the solvent recovery system as specified in paragraph (e)(5)(vi) of this section.

(i) For each solvent recovery system, install, calibrate, maintain, and operate according to the manufacturer's specifications, a device that indicates the cumulative amount of volatile organic matter recovered by the solvent recovery system for the compliance period. The device must be initially certified by the manufacturer to be accurate to within ±2.0 percent of the mass of volatile organic matter recovered.

(ii) For each solvent recovery system, determine the mass of volatile organic matter recovered for the compliance period, kg, based on measurement with the device required in paragraph (e)(5)(i) of this section.

(iii) Determine the mass fraction of volatile organic matter for each coating, printing, cleaning, and thinning material applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period, kg volatile organic matter per kg coating, printing, cleaning, and thinning material. You may determine the volatile organic matter mass fraction using Method 24 of 40 CFR part 60, appendix A, or an EPA approved alternative method, or you may use information provided by the manufacturer or supplier of the coating or printing material. In the event of any inconsistency between information provided by the manufacturer or supplier and the results of Method 24 of 40 CFR part 60, appendix A, or an approved alternative method, the test method results will govern.

(iv) Measure the mass of each coating, printing, thinning, and cleaning material applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period, kg.

(v) For the compliance period, calculate the solvent recovery system's volatile organic matter collection and recovery efficiency using Equation 2 of this section:

$$R_V = 100 \frac{M_{VR}}{\sum_{i=1}^{m} M_i WV_{c,i} + \sum_{j=1}^{n} M_j WV_{t,j}} \qquad \text{(Eq. 2)}$$

Where:

R_V = Volatile organic matter collection and recovery efficiency of the solvent recovery system during the compliance period, percent.

M_{VR} = Mass of volatile organic matter recovered by the solvent recovery system during the compliance period, kg.

M_i = Mass of coating or printing material, i, applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period, kg.

$WV_{c,i}$ = Mass fraction of volatile organic matter for coating or printing material, i, kg volatile organic matter per kg coating or printing material.

M_j = Mass of thinning or cleaning material, j, applied in the web coating/printing operation controlled by the solvent recovery

system during the compliance period, kg.

$WV_{t,j}$ = Mass fraction of volatile organic matter for thinning or cleaning material, j, kg volatile organic matter per kg thinning or cleaning material.

m = Number of different coating and printing materials applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period.

n = Number of different thinning and cleaning materials applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period.

(vi) Calculate the mass of organic HAP emission reductions for the web coating/printing operation controlled by the solvent recovery system during the compliance period using Equation 3 of this section and according to paragraphs (e)(5)(vi)(A) and (B) of this section:

$$H_{CSR} = \left(A_{CSR} + B_{CSR}\right)\left(\frac{R_V}{100}\right) \qquad \text{(Eq. 3)}$$

Where:

H_{CSR} = Mass of organic HAP emission reduction for the web coating/printing operation controlled by the solvent recovery system during the compliance period, kg.

A_{CSR} = Total mass of organic HAP in the coating and printing material applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period, kg, calculated using Equation 3A of this section.

B_{CSR} = Total mass of organic HAP in the thinning and cleaning materials applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period, kg, calculated using Equation 3B of this section.

R_V = Volatile organic matter collection and recovery efficiency of the solvent recovery system, percent, from Equation 2 of this section.

(A) Calculate the total mass of organic HAP in the coating and printing materials applied in the web coating/printing operation(s) controlled by the solvent recovery system during the compliance period, kg, using Equation 3A of this section:

$$A_{CSR} = \sum_{i=1}^{m}\left(M_{c,i}\right)\left(W_{c,i}\right) \qquad \text{(Eq. 3A)}$$

Where:

A_{CSR} = Total mass of organic HAP in the coating and printing materials applied in the web coating/printing operations(s) controlled by the solvent recovery system during the compliance period, kg.

$M_{c,i}$ = Mass of coating or printing material, i, applied during the compliance period in the web coating/printing operation(s) controlled by the solvent recovery system, kg.

$W_{c,i}$ = Mass fraction of organic HAP in coating or printing material, i, kg per kg.

m = Number of different coating and printing materials applied during compliance period.

(B) Calculate the total mass of organic HAP in the thinning and cleaning materials applied in the web coating/printing operation(s) controlled by the solvent recovery system during the compliance period, kg, using Equation 3B of this section:

$$B_{CSR} = \sum_{j=1}^{n}\left(M_{t,j}\right)\left(W_{t,j}\right) \qquad \text{(Eq. 3B)}$$

Where:

B_{CSR} = Total mass of organic HAP in the thinning and cleaning materials applied in the web coating/printing operation(s) controlled by the solvent recovery system during the compliance period, kg.

$M_{t,j}$ = Total mass of thinning or cleaning material, j, applied during the compliance period in the web coating/printing operation(s) controlled by the solvent recovery system, kg.

$W_{t,j}$ = Mass fraction of organic HAP in thinning or cleaning material, j, kg per kg.

n = Number of different thinning and cleaning materials applied during the compliance period.

(6) *Calculate the total mass of coating and printing solids.* Determine the total mass of coating and printing solids applied, kg, which is the combined mass of the solids contained in all the coating and printing material applied during the compliance period in the web coating/printing operation(s) for which you use the emission rate with add-on controls option, using Equation 2 of § 63.4331.

(7) *Calculate the organic HAP emission rate with add-on controls for the compliance period.* Determine the organic HAP emission rate with add-on controls for the compliance period, kg organic HAP emitted per kg solids applied during the compliance period, using Equation 4 of this section.

$$H_{HAP} = \frac{H_e - \sum_{i=1}^{q}\left(H_{C,i}\right) - \sum_{j=i}^{r}\left(H_{CSR,j}\right)}{H_t} \qquad \text{(Eq. 4)}$$

Where:

H_{HAP} = Organic HAP emission rate with add-on controls for the compliance period, kg organic HAP emitted per kg solids applied.

H_e = Total mass of organic HAP emissions before add-on controls from all the coating, printing, thinning, and cleaning materials applied during the compliance period, kg, determined according to paragraph (e)(2) of this section.

$H_{C,i}$ = Total mass of organic HAP emissions reduction for controlled web coating/printing operation, i, not using a liquid-liquid material balance, during the compliance period, kg, from Equation 1 of this section.

$H_{CSR,j}$ = Total mass of organic HAP emissions reduction for web coating/printing operation, j, controlled by a solvent recovery system using a liquid-liquid material balance, during the compliance period, kg, from Equation 3 of this section.

H_t = Total mass of coating and printing solids applied during the compliance period, kg, from Equation 2 of § 63.4331.

q = Number of controlled web coating/printing operations not using a liquid-liquid material balance.

r = Number of web coating/printing operations controlled by a solvent recovery system using a liquid-liquid material balance.

(8) *Compliance demonstration.* To demonstrate initial compliance with the emission limit, the organic HAP emission rate with add-on controls for the compliance period, calculated using Equation 4 of this section, must be less

than or equal to the applicable emission limit in Table 1 to this subpart. You must keep all records as required by §§ 63.4312 and 63.4313. As part of the Notification of Compliance Status required by § 63.4310, you must identify the web coating/printing operation(s) for which you used the emission rate with add-on controls option and submit a statement that the web coating/printing operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP emission rate was less than or equal to the applicable emission limit in Table 1 to this subpart, and that you achieved the operating limits required by § 63.4292 and the work practice standards required by § 63.4293.

(f) *Compliance with dyeing/finishing emission limits.* You must follow the procedures in paragraphs (f)(1) through (8) of this section to demonstrate compliance with the applicable dyeing/finishing emission limit in Table 1 to this subpart.

(1) *Determine the mass fraction of organic HAP and mass of materials.* Follow the procedures specified in § 63.4331(b)(1) and (2) to determine the mass fraction of organic HAP for each dyeing and finishing material applied and mass of each dyeing and finishing material applied during the compliance period.

(2) *Calculate the mass of organic HAP emissions before add-on controls.* Using Equation 4 of § 63.4331, calculate the mass of organic HAP emissions before add-on controls from all dyeing and finishing materials applied during the compliance period minus the organic HAP in certain waste materials and wastewaters in the dyeing/finishing operation or group of dyeing/finishing operations for which you use the emission rate with add-on controls option.

(3) *Calculate the organic HAP emissions reductions for each controlled dyeing/finishing operation.* Determine the mass of organic HAP emissions reduced for each controlled dyeing/finishing operation during the compliance period. The emissions reductions determination quantifies the total organic HAP emissions that pass through the emission capture system and are destroyed or removed by the add-on control device. Use the procedures in paragraph (f)(4) of this section to calculate the mass of organic HAP emissions reductions for each controlled dyeing/finishing operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances. For each controlled dyeing/finishing operation using a solvent recovery system for which you conduct a liquid-liquid material balance, use the procedures in paragraph (f)(5) of this section to calculate the organic HAP emissions reductions.

(4) *Calculate the organic HAP emission reduction for each controlled dyeing/finishing operation not using liquid-liquid material balance.* For each controlled dyeing/finishing operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances, calculate the organic HAP emissions reductions using Equation 5 of this section. The equation applies the emission capture system efficiency and add-on control device efficiency to the mass of organic HAP contained in the dyeing and finishing materials applied in the dyeing/finishing operation served by the emission capture system and add-on control device during the compliance period. For any period of time a deviation specified in § 63.4342(c) or (d) occurs in the controlled dyeing/finishing operation, including a deviation during startup, shutdown, or malfunction, then you must assume zero efficiency for the emission capture system and add-on control device. Equation 5 of this section treats the dyeing and finishing materials applied during such a deviation as if they were applied on an uncontrolled dyeing/finishing operation for the time period of the deviation.

$$H_C = \left(A_I - H_{UNC}\right)\left(\frac{CE}{100} \times \frac{DRE}{100}\right) \quad \text{(Eq. 5)}$$

Where:

H_C = Mass of organic HAP emission reduction for the controlled dyeing/finishing operation during the compliance period, kg.

A_I = Total mass of organic HAP in the dyeing and finishing materials applied in the controlled dyeing/finishing operation during the compliance period, kg, as calculated in Equation 5A of this section.

H_{UNC} = Total mass of organic HAP in the dyeing and finishing materials applied during all deviations specified in § 63.4342(c) and (d) that occurred during the compliance period in the controlled dyeing/finishing operation, kg, as calculated in Equation 5B of this section.

CE = Capture efficiency of the emission capture system vented to the add-on control device, percent. Use the test methods and procedures specified in §§ 63.4360 and 63.4361 to measure and record capture efficiency.

DRE = Organic HAP destruction or removal efficiency of the add-on control device, percent. Use the test methods and procedures in §§ 63.4360 and 63.4362 to measure and record the organic HAP destruction or removal efficiency.

(i) Calculate the total mass of organic HAP in the dyeing and finishing materials applied in the controlled dyeing/finishing operation(s) during the compliance period, kg, using Equation 5A of this section:

$$A_I = \sum_{i=1}^{m}\left(M_{c,i}\right)\left(W_{c,i}\right) \quad \text{(Eq. 5A)}$$

Where:

A_I = Total mass of organic HAP in the dyeing and finishing materials applied in the controlled dyeing/finishing operations(s) during the compliance period, kg.

$M_{c,i}$ = Mass of dyeing or finishing material, i, applied during the compliance period, kg.

$W_{c,i}$ = Mass fraction of organic HAP in dyeing or finishing material, i, kg per kg.

m = Number of different dyeing and finishing materials applied during compliance period.

(ii) Calculate the mass of organic HAP in the dyeing and finishing materials applied in the controlled dyeing/finishing operation during deviations specified in § 63.4342(c) and (d), using Equation 5B of this section.

$$H_{UNC} = \sum_{h=1}^{q}\left(M_h\right)\left(W_h\right) \quad \text{(Eq. 5B)}$$

Where:

H_{UNC} = Total mass of organic HAP in the dyeing and finishing materials applied during all deviations specified in § 63.4342(c) and (d) that occurred during the compliance period in the controlled dyeing/finishing operation, kg.

M_h = Total mass of dyeing and finishing material, h, applied in the controlled dyeing/finishing operation during deviations, kg.

W_h = Mass fraction of organic HAP in dyeing or finishing material, h, kg organic HAP per kg material.

q = Number of different dyeing and finishing materials applied.

(5) *Calculate the organic HAP emissions reductions for controlled dyeing/finishing operation using liquid-liquid material balances.* For each controlled dyeing/finishing operation using a solvent recovery system for which you conduct liquid-liquid

material balances, calculate the organic HAP emissions reductions by applying the volatile organic matter collection and recovery efficiency to the mass of organic HAP contained in the dyeing and finishing materials applied in the dyeing/finishing operation controlled by the solvent recovery system during the compliance period. Perform a liquid-liquid material balance for the compliance period as specified in paragraphs (f)(5)(i) through (v) of this section. Calculate the mass of organic HAP emissions reductions by the solvent recovery system as specified in paragraph (f)(5)(vi) of this section.

(i) For each solvent recovery system, install, calibrate, maintain, and operate according to the manufacturer's specifications, a device that indicates the cumulative amount of volatile organic matter recovered by the solvent recovery system for the compliance period. The device must be initially certified by the manufacturer to be accurate to within ±2.0 percent of the mass of volatile organic matter recovered.

(ii) For each solvent recovery system, determine the mass of volatile organic matter recovered for the compliance period, kg, based on measurement with the device required in paragraph (f)(5)(i) of this section.

(iii) Determine the mass fraction of volatile organic matter for each dyeing and finishing material applied in the dyeing/finishing operation controlled by the solvent recovery system during the compliance period, kg volatile organic matter per kg dyeing and finishing material. You may determine the volatile organic matter mass fraction using information provided by the manufacturer or supplier of the dyeing or finishing material.

(iv) Measure the mass of each dyeing and finishing material applied in the dyeing/finishing operation controlled by the solvent recovery system during the compliance period, kg.

(v) For the compliance period, calculate the solvent recovery system's volatile organic matter collection and recovery efficiency using Equation 6 of this section:

$$R_V = 100 \frac{M_{VR}}{\sum_{i=1}^{m} M_i WV_{c,i}} \qquad \text{(Eq. 6)}$$

Where:

R_V = Volatile organic matter collection and recovery efficiency of the solvent recovery system during the compliance period, percent.

M_{VR} = Mass of volatile organic matter recovered by the solvent recovery system during the compliance period, kg.

M_i = Mass of dyeing or finishing material, i, applied in the dyeing/finishing operation controlled by the solvent recovery system during the compliance period, kg.

$WV_{c,i}$ = Mass fraction of volatile organic matter for dyeing or finishing material, i, kg volatile organic matter per kg dyeing or finishing material.

m = Number of different dyeing and finishing materials applied in the dyeing/finishing operation controlled by the solvent recovery system during the compliance period.

(vi) Calculate the mass of organic HAP emission reductions for the dyeing/finishing operation controlled by the solvent recovery system during the compliance period using Equation 7 of this section and according to paragraph (f)(5)(vi)(A) of this section:

$$H_{CSR} = \left(A_{CSR}\right)\left(\frac{R_V}{100}\right) \qquad \text{(Eq. 7)}$$

Where:

H_{CSR} = Mass of organic HAP emission reduction for the dyeing/finishing operation controlled by the solvent recovery system during the compliance period, kg.

A_{CSR} = Total mass of organic HAP in the dyeing and finishing material applied in the dyeing/finishing operation controlled by the solvent recovery system during the compliance period, kg, calculated using Equation 7A of this section.

R_V = Volatile organic matter collection and recovery efficiency of the solvent recovery system, percent, from Equation 6 of this section.

(A) Calculate the total mass of organic HAP in the dyeing and finishing materials applied in the dyeing/finishing operation(s) controlled by the solvent recovery system during the compliance period, kg, using Equation 7A of this section:

$$A_{CSR} = \sum_{i=1}^{m}\left(M_{c,i}\right)\left(W_{c,i}\right) \qquad \text{(Eq. 7A)}$$

Where:

A_{CSR} = Total mass of organic HAP in the dyeing and finishing materials applied in the dyeing/finishing operations(s) controlled by the solvent recovery system during the compliance period, kg.

$M_{c,i}$ = Mass of dyeing or finishing material, i, applied during the compliance period in the dyeing/finishing operation(s) controlled by the solvent recovery system, kg.

$W_{c,i}$ = Mass fraction of organic HAP in dyeing or finishing material, i, kg per kg.

m = Number of different dyeing and finishing materials applied during compliance period.

(6) *Calculate the total mass of dyeing and finishing materials.* Determine the total mass of dyeing and finishing materials applied, kg, which is the combined mass of all the dyeing and finishing materials applied during the compliance period in the dyeing/finishing operation(s) for which you use the emission rate with add-on controls option, using Equation 5 of § 63.4331.

(7) *Calculate the organic HAP emission rate with add-on controls for the compliance period.* Determine the organic HAP emission rate with add-on controls for the compliance period, kg organic HAP emitted per kg dyeing and finishing materials applied during the compliance period, using Equation 8 of this section.

$$H_{HAP} = \frac{H_e - \sum_{i=1}^{q}\left(H_{C,i}\right) - \sum_{j=1}^{r}\left(H_{CSR,j}\right)}{M_t} \qquad \text{(Eq. 8)}$$

Where:

H_{HAP} = Organic HAP emission rate with add-on controls for the compliance period, kg organic HAP emitted per kg dyeing and finishing materials applied.

H_e = Total mass of organic HAP emissions before add-on controls from all the dyeing and finishing materials applied during the compliance period, kg, determined according to paragraph (f)(2) of this section.

$H_{C,i}$ = Total mass of organic HAP emissions reductions for controlled dyeing/finishing operation, i, not using a liquid-liquid material balance, during the compliance period, kg, from Equation 5 of this section.

$H_{CSR,j}$ = Total mass of organic HAP emissions reductions for dyeing/finishing operation, j, controlled by a solvent recovery system using a liquid-liquid material balance, during the compliance period, kg, from Equation 7 of this section.

M_t = Total mass of dyeing and finishing materials applied during the compliance period, kg, from Equation 5 of § 63.4331.

q = Number of controlled dyeing/finishing operations not using a liquid-liquid material balance.

r = Number of dyeing/finishing operations controlled by a solvent recovery system using a liquid-liquid material balance.

(8) *Compliance demonstration.* To demonstrate initial compliance with the emission limit, the organic HAP emission rate with add-on controls for the compliance period, calculated using Equation 8 of this section, must be less than or equal to the applicable emission limit in Table 1 to this subpart. You must keep all records as required by §§ 63.4312 and 63.4313. As part of the Notification of Compliance Status required by § 63.4310, you must identify the dyeing/finishing operation(s) for which you used the emission rate with add-on controls option and submit a statement that the dyeing/finishing operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP emission rate was less than or equal to the applicable emission limit in Table 1 to this subpart, and that you achieved the operating limits required by § 63.4292 and the work practice standards required by § 63.4293.

§ 63.4342 How do I demonstrate continuous compliance with the emission limitations?

(a) To demonstrate continuous compliance with the applicable emission limit in Table 1 to this subpart, the organic HAP emission rate for each compliance period, determined according to § 63.4341(e) for web coating/printing operations and according to § 63.4341(f) for dyeing/finishing operations, must be equal to or less than the applicable emission limit in Table 1 to this subpart. Each month following the initial compliance period described in § 63.4340 is a compliance period consisting of that month and the preceding 11 months. You must perform the calculations in § 63.4341 on a monthly basis.

(b) If the organic HAP emission rate with add-on controls for any compliance period exceeded the applicable emission limit in Table 1 to this subpart, this is a deviation from the emission limitation for that compliance period and must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(7).

(c) You must demonstrate continuous compliance with each operating limit required by § 63.4292 that applies to you, as specified in Table 2 to this subpart.

(1) If an operating parameter is out of the allowed range specified in Table 2 to this subpart, this is a deviation from the operating limit that must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(7).

(2) If an operating parameter deviates from the operating limit specified in Table 2 to this subpart, then you must assume that the emission capture system and add-on control device were achieving zero efficiency during the time period of the deviation. For the purposes of completing the compliance calculations specified in § 63.4341 (e)(4) and (f)(4), you must treat the regulated materials applied during a deviation on a controlled coating/printing or dyeing/finishing operation as if they were applied on an uncontrolled coating/printing or dyeing/finishing operation for the time period of the deviation, as indicated in Equation 1 of § 63.4341 for a web coating/printing operation, and in Equation 5 of § 63.4341 for a dyeing/finishing operation.

(d) You must meet the requirements for bypass lines in § 63.4364(b) for controlled coating/printing or dyeing/finishing operations for which you do not conduct liquid-liquid material balances. If any bypass line is opened and emissions are diverted to the atmosphere when the web coating/printing or dyeing/finishing operation is running, this is a deviation that must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(7). For the purposes of completing the compliance calculations specified in § 63.4341(e)(4), you must treat the coating, printing, thinning, and cleaning materials applied during a deviation on a controlled web coating/printing operation as if they were used on an uncontrolled web coating/printing operation for the time period of the deviation, as indicated in Equation 1 of § 63.4341. For the purposes of completing the compliance calculations specified in § 63.4341(f)(4), you must treat the dyeing and finishing materials applied during a deviation on a controlled dyeing/finishing operation as if they were used on an uncontrolled dyeing/finishing operation for the time period of the deviation, as indicated in Equation 5 of § 63.4341.

(e) You must demonstrate continuous compliance with the work practice standards in § 63.4293. If you did not develop a work practice plan, or you did not implement the plan, or you did not keep the records required by § 63.4312(j)(8), this is a deviation from the work practice standards that must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(7).

(f) As part of each semiannual compliance report required in § 63.4311, you must identify the coating/printing and dyeing/finishing operation(s) for which you use the emission rate with add-on controls option. If there were no deviations from the applicable emission limit in Table 1 to this subpart, you must submit a statement that, as appropriate, the web coating/printing operations or the dyeing/finishing operations were in compliance with the emission limitations during the reporting period because the organic HAP emission rate for each compliance period was less than or equal to the applicable emission limit in Table 1 to this subpart, and you achieved the operating limits required by § 63.4292 and the work practice standards required by § 63.4293 during each compliance period.

(g) During periods of startup, shutdown, or malfunction of the emission capture system, add-on control device, or web coating/printing or dyeing/finishing operation that may affect emission capture or control device efficiency, you must operate in accordance with the startup, shutdown, and malfunction plan required by § 63.4300(c).

(h) Consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of startup, shutdown, or malfunction of the emission capture system, add-on control device, or web coating/printing or dyeing/finishing operation that may affect emission capture or control device efficiency are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with the startup, shutdown, and malfunction plan. The Administrator will determine whether deviations that occur during a period of startup, shutdown, or malfunction are violations according to the provisions in § 63.6(e).

(i) [Reserved]

(j) You must maintain records as specified in §§ 63.4312 and 63.4313.

Compliance Requirements for the Organic HAP Overall Control Efficiency and Oxidizer Outlet Organic HAP Concentration Options

§ 63.4350 By what date must I conduct performance tests and other initial compliance demonstrations?

(a) *New and reconstructed affected sources.* For a new or reconstructed affected source, you must meet the requirements of paragraphs (a)(1) through (4) of this section.

(1) All emission capture systems, add-on control devices, and CPMS must be installed and operating no later than the applicable compliance date specified in § 63.4283. Except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4351(d)(5), you must conduct a performance test of each capture system and add-on control device according to the procedures in §§ 63.4360, 63.4361, and 63.4362, and establish the operating limits required by § 63.4292, within 180 days of the applicable compliance date specified in § 63.4283. For a solvent recovery system for which you conduct liquid-liquid material balances according to § 63.4351(d)(5), you must initiate the first material balance no later than the applicable compliance date specified in § 63.4283.

(2) You must develop and begin implementing the work practice plan required by § 63.4293 no later than the compliance date specified in § 63.4283.

(3) You must complete the compliance demonstration for the initial compliance period according to the requirements of § 63.4351. The initial compliance period begins on the applicable compliance date specified in § 63.4283 and ends on the last day of the first full month after the compliance date, or the date you conduct the performance tests of the emission capture systems and add-on control devices, or initiate the first liquid-liquid material balance for a solvent recovery system, whichever is later. The initial compliance demonstration includes the results of emission capture system and add-on control device performance tests conducted according to §§ 63.4360, 63.4361, and 63.4362; results of liquid-liquid material balances conducted according to § 63.4351(d)(5); calculations according to § 63.4351 and supporting documentation showing that during the initial compliance period either the organic HAP overall control efficiency was equal to or greater than the applicable overall control efficiency limit in Table 1 to this subpart or the oxidizer outlet organic HAP concentration was no greater than 20 parts per million by weight (ppmw) on a dry basis; the operating limits established during the performance tests and the results of the continuous parameter monitoring required by § 63.4364; and documentation of whether you developed and implemented the work practice plan required by § 63.4293.

(4) You do not need to comply with the operating limits for the emission capture system and add-on control device required by § 63.4292 until after you have completed the performance tests specified in paragraph (a)(1) of this section. Instead, you must maintain a log detailing the operation and maintenance of the emission capture system, add-on control device, and continuous parameter monitors during the period between the compliance date and the performance test. You must begin complying with the operating limits for your affected source on the date you complete the performance tests specified in paragraph (a)(1) of this section. This requirement does not apply to solvent recovery systems for which you conduct liquid-liquid material balances according to the requirements of § 63.4351(d)(5).

(b) *Existing sources.* For an existing affected source, you must meet the requirements of paragraphs (b)(1) through (3) of this section.

(1) All emission capture systems, add-on control devices, and CPMS must be installed and operating no later than the applicable compliance date specified in § 63.4283. Except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4351(d)(5), you must conduct a performance test of each capture system and add-on control device according to the procedures in §§ 63.4360, 63.4361, and 63.4362, and establish the operating limits required by § 63.4292, within 180 days of the compliance date specified in § 63.4283. For a solvent recovery system for which you conduct liquid-liquid material balances according to § 63.4351(d)(5), you must initiate the first material balance no later than the compliance date specified in § 63.4283.

(2) You must develop and begin implementing the work practice plan required by § 63.4293 no later than the compliance date specified in § 63.4283.

(3) You must complete the compliance demonstration for the initial compliance period according to the requirements of § 63.4351. The initial compliance period begins on the applicable compliance date specified in § 63.4283 and ends on the last day of the first full month after the compliance date. The initial compliance demonstration includes the results of emission capture system and add-on control device performance tests conducted according to §§ 63.4360, 63.4361, and 63.4362; results of liquid-liquid material balances conducted according to § 63.4351(d)(5); calculations according to § 63.4351 and supporting documentation showing that during the initial compliance period the organic HAP overall control efficiency was equal to or greater than the applicable organic HAP overall control efficiency limit in Table 1 to this subpart or the oxidizer outlet organic HAP concentration was no greater than 20 ppmw on a dry basis and the efficiency of the capture system was 100 percent; the operating limits established during the performance tests and the results of the continuous parameter monitoring required by § 63.4364; and documentation of whether you developed and implemented the work practice plan required by § 63.4293.

§ 63.4351 How do I demonstrate initial compliance?

(a) You may use the organic HAP overall control efficiency option or the oxidizer outlet organic HAP concentration option for any individual web coating/printing operation, for any group of web coating/printing operations in the affected source, or for all of the web coating/printing operations in the affected source. You may include both controlled and uncontrolled web coating/printing operations in a group for which you use the organic HAP overall control efficiency option. You must use either the compliant material option, the emission rate without add-on controls option, or the emission rate with add-on controls option for any web coating/printing operation(s) in the affected source for which you do not use either the organic HAP overall control efficiency option or the oxidizer outlet organic HAP concentration option. To demonstrate initial compliance, any web coating/printing operation for which you use the organic HAP overall control efficiency option must meet the applicable organic HAP overall control efficiency limitations in Table 1 to this subpart according to the procedures in paragraph (d) of this section. Any web coating/printing operation for which you use the oxidizer outlet organic HAP concentration option must meet the 20 ppmw on a dry basis limit and achieve 100 percent capture efficiencies according to the procedures in paragraph (e) of this section. To demonstrate initial compliance with either option, you also must meet the applicable operating limits in § 63.4292 according to the procedures in paragraph (b) of this section and the

work practice standards in § 63.4293 according to the procedures in paragraph (c) of this section. When calculating the organic HAP overall control efficiency according to this section, do not include any coating, printing, thinning, or cleaning materials applied on web coating/printing operations for which you use the compliant material option, the emission rate without add-on controls option, the emission rate with add-on controls option, or the oxidizer outlet organic HAP concentration option. You do not need to redetermine the mass of organic HAP in coating, printing, thinning, or cleaning materials that have been reclaimed onsite and reused in web coating/printing operation(s) for which you use the organic HAP overall control efficiency option.

(b) *Compliance with operating limits.* Except as provided in § 63.4350(a)(4), and except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4351(d)(5), you must establish and demonstrate continuous compliance during the initial compliance period with the operating limits required by § 63.4292, using the procedures specified in §§ 63.4363 and 63.4364.

(c) *Compliance with work practice requirements.* You must develop, implement, and document your implementation of the work practice plan required by § 63.4293 during the initial compliance period as specified in § 63.4312.

(d) *Compliance with organic HAP overall control efficiency limits.* You must follow the procedures in paragraphs (d)(1) through (7) of this section to demonstrate compliance with the applicable organic HAP overall control efficiency limit in Table 1 to this subpart.

(1) *Determine the mass fraction of organic HAP and mass of coating or printing materials.* Follow the procedures specified in § 63.4331(a)(1) and (3) to determine the mass fraction of organic HAP and mass of each coating, printing, thinning, and cleaning material applied during the compliance period.

(2) *Calculate the total mass of organic HAP emissions before add-on controls.* Using Equation 1 of § 63.4331, calculate the total mass of organic HAP emissions before add-on controls from all coating, printing, thinning, and cleaning materials applied during the compliance period minus the organic HAP in certain waste materials in the web coating/printing operation or group of web coating/printing operations for which you use the organic HAP overall control efficiency option.

(3) *Calculate the organic HAP emissions reductions for each controlled web coating/printing operation.* Determine the mass of organic HAP emissions reduced for each controlled web coating/printing operation during the compliance period. The emissions reductions determination quantifies the total organic HAP emissions that pass through the emission capture system and are destroyed or removed by the add-on control device. Use the procedures in paragraph (d)(4) of this section to calculate the mass of organic HAP emissions reductions for each controlled web coating/printing operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances. For each controlled web coating/printing operation using a solvent recovery system for which you conduct a liquid-liquid material balance, use the procedures in paragraph (d)(5) of this section to calculate the organic HAP emissions reductions.

(4) *Calculate the organic HAP emissions reductions for controlled web coating/printing operations not using liquid-liquid material balance.* For each controlled web coating/printing operation using an emission capture system and add-on control device other than a solvent recovery system for which you conduct liquid-liquid material balances, calculate the organic HAP emissions reductions using Equation 1 of § 63.4341. The equation applies the emission capture system efficiency and add-on control device efficiency to the mass of organic HAP contained in the coating, printing, thinning, and cleaning materials applied in the web coating/printing operation served by the emission capture system and add-on control device during the compliance period. For any period of time a deviation specified in § 63.4352(c) or (d) occurs in the controlled web coating/printing operation, including a deviation during startup, shutdown, or malfunction, then you must assume zero efficiency for the emission capture system and add-on control device. Equation 1 of § 63.4341 treats the coating, printing, thinning, and cleaning materials applied during such a deviation as if they were applied on an uncontrolled web coating/printing operation for the time period of the deviation.

(i) Calculate the total mass of organic HAP in the coating and printing material(s) applied in the controlled web coating/printing operation during the compliance period, kg, using Equation 1A of § 63.4341.

(ii) Calculate the total mass of organic HAP in the thinning and cleaning materials applied in the controlled web coating/printing operation(s) during the compliance period, kg, using Equation 1B of § 63.4341.

(iii) Calculate the mass of organic HAP in the coating, printing, thinning, and cleaning materials applied in the controlled web coating/printing operation during deviations specified in § 63.4352(c) and (d), using Equation 1C of § 63.4341.

(5) *Calculate the organic HAP emissions reductions for controlled web coating/printing operations using liquid-liquid material balance.* For each controlled web coating/printing operation using a solvent recovery system for which you conduct liquid-liquid material balances, calculate the organic HAP emissions reductions by applying the volatile organic matter collection and recovery efficiency to the mass of organic HAP contained in the coating, printing, thinning, and cleaning materials applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period. Perform a liquid-liquid material balance for the compliance period as specified in paragraphs (d)(5)(i) through (vi) of this section.

(i) For each solvent recovery system, install, calibrate, maintain, and operate according to the manufacturer's specifications, a device that indicates the cumulative amount of volatile organic matter recovered by the solvent recovery system for the compliance period. The device must be initially certified by the manufacturer to be accurate to within ±2.0 percent of the mass of volatile organic matter recovered.

(ii) For each solvent recovery system, determine the mass of volatile organic matter recovered for the compliance period, kg, based on measurement with the device required in paragraph (d)(5)(i) of this section.

(iii) Determine the mass fraction of volatile organic matter for each coating and printing material applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period, kg volatile organic matter per kg coating and printing material. You may determine the volatile organic matter mass fraction using Method 24 of 40 CFR part 60, appendix A, or an EPA approved alternative method, or you may use information provided by the manufacturer or supplier of the coating or printing material. In the event of any inconsistency between information provided by the manufacturer or

supplier and the results of Method 24 of 40 CFR part 60, appendix A, or an approved alternative method, the test method results will govern.

(iv) Measure the mass of each coating, printing, thinning, and cleaning material applied in the web coating/printing operation controlled by the solvent recovery system during the compliance period, kg.

(v) For the compliance period, calculate the solvent recovery system's volatile organic matter collection and recovery efficiency using Equation 2 of § 63.4341.

(vi) Calculate the mass of organic HAP emissions reductions for the web coating/printing operation controlled by the solvent recovery system during the compliance period, using Equation 3 of § 63.4341.

(6) *Calculate the organic HAP overall control efficiency.* Determine the organic HAP overall control efficiency, kg organic HAP emissions reductions per kg organic HAP emissions before add-on controls during the compliance period, using Equation 1 of this section.

$$E_{HAP} = \frac{\sum_{i=1}^{q}\left(H_{C,i}\right) + \sum_{j=1}^{r}\left(H_{CSR,j}\right)}{H_e} \times 100 \qquad \text{(Eq. 1)}$$

Where:

E_{HAP} = Organic HAP overall control efficiency for the compliance period, kg organic HAP emissions reductions per kg organic HAP emissions before add-on controls during the compliance period.

$H_{C,i}$ = Total mass of organic HAP emissions reductions for controlled web coating/printing operation, i, during the compliance period, kg, from Equation 1 of § 63.4341.

$H_{CSR,j}$ = Total mass of organic HAP emissions reductions for controlled web coating/printing operation, j, during the compliance period, kg, from Equation 3 of § 63.4341.

H_e = Total mass of organic HAP emissions before add-on controls from all the coating, printing, thinning, and cleaning materials applied during the compliance period, kg, determined according to paragraph (d)(2) of this section.

q = Number of controlled web coating/printing operations except those controlled with a solvent recovery system.

r = Number of web coating/printing operations controlled with a solvent recovery system.

(7) *Compliance demonstration.* To demonstrate initial compliance with the organic HAP overall control efficiency in Table 1 to this subpart, the organic HAP overall control efficiency calculated using Equation 1 of this section must be at least 98 percent for new or reconstructed affected sources and at least 97 percent for existing affected sources. You must keep all records as required by §§ 63.4312 and 63.4313. As part of the Notification of Compliance Status required by § 63.4310, you must identify the web coating/printing operation(s) for which you used the organic HAP overall control efficiency option and submit a statement that the web coating/printing operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP overall control efficiency was greater than or equal to the applicable organic HAP overall control efficiency in Table 1 to this subpart, and you achieved the operating limits required by § 63.4292 and the work practice standards required by § 63.4293.

(e) *Compliance with oxidizer outlet organic HAP concentration limit.* You must follow the procedures in paragraphs (e)(1) through (3) of this section to demonstrate compliance with the oxidizer outlet organic HAP concentration limit of no greater than 20 ppmw on a dry basis.

(1) *Install and operate a PTE.* Install and operate a PTE around each work station and associated drying or curing oven in the web coating/printing operation. An enclosure that meets the requirements in § 63.4361(a) is considered a PTE. Route all organic HAP emissions from each PTE to an oxidizer.

(2) *Determine oxidizer outlet organic HAP concentration.* Determine oxidizer outlet organic HAP concentration through performance tests using the procedures in § 63.4362(a) and (b).

(3) *Compliance demonstration.* To demonstrate initial compliance with the oxidizer outlet organic HAP concentration limit in Table 1 to this subpart, the oxidizer outlet organic HAP concentration must be no greater than 20 ppmv on a dry basis and the efficiency of the capture system must be 100 percent. You must keep all records as required by §§ 63.4312 and 63.4313. As part of the Notification of Compliance Status required by § 63.4310, you must identify the web coating/printing operation(s) for which you used the oxidizer outlet organic HAP concentration option and submit a statement that the web coating/printing operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the oxidizer outlet organic HAP concentration was no greater than 20 ppmv on a dry basis, the efficiency of the capture system was 100 percent, and you achieved the operating limits required by § 63.4292 and the work practice standards required by § 63.4293.

§ 63.4352 How do I demonstrate continuous compliance with the emission limitations?

(a) You must meet all the requirements of this section to demonstrate continuous compliance with the organic HAP overall control efficiency. The organic HAP overall control efficiency for each compliance period, determined according to the procedures in § 63.4351(d), must be equal to or greater than the applicable organic HAP overall control efficiency limit in Table 1 to this subpart. Each month following the initial compliance period described in § 63.4350 is a compliance period. You must perform the calculations in § 63.4351(d) on a monthly basis. You must meet the applicable requirements of paragraphs (c) through (j) of this section to demonstrate continuous compliance with the oxidizer outlet organic HAP concentration limit.

(b) If the organic HAP overall control efficiency for any compliance period failed to meet the applicable organic HAP overall control efficiency in Table 1 to this subpart, this is a deviation from the emission limitation for that compliance period and must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(7).

(c) You must demonstrate continuous compliance with each operating limit required by § 63.4292 that applies to you, as specified in Table 2 to this subpart.

(1) If an operating parameter is out of the allowed range specified in Table 2

to this subpart, this is a deviation from the operating limit that must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(7).

(2) If an operating parameter deviates from the operating limit specified in Table 2 to this subpart, then you must assume that the emission capture system and add-on control device were achieving zero efficiency during the time period of the deviation. For the purposes of completing the compliance calculations specified in § 63.4351(d)(4), you must treat the coating, printing, thinning, and cleaning materials applied during a deviation on a controlled web coating/printing operation as if they were applied on an uncontrolled web coating/printing operation for the time period of the deviation as indicated in Equation 1 of § 63.4341.

(d) You must meet the requirements for bypass lines in § 63.4364(b) for controlled web coating/printing operations for which you do not conduct liquid-liquid material balances. If any bypass line is opened and emissions are diverted to the atmosphere when the web coating/printing operation is running, this is a deviation that must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(7). For the purposes of completing the compliance calculations specified in § 63.4351(d)(4), you must treat the coating, printing, thinning, and cleaning materials applied during a deviation on a controlled web coating/printing operation as if they were applied on an uncontrolled web coating/printing operation for the time period of the deviation as indicated in Equation 1 of § 63.4341.

(e) You must demonstrate continuous compliance with the work practice standards in § 63.4293. If you did not develop a work practice plan, or you did not implement the plan, or you did not keep the records required by § 63.4312(j)(8), this is a deviation from the work practice standards that must be reported as specified in §§ 63.4310(c)(6) and 63.4311(a)(7).

(f) As part of each semiannual compliance report required in § 63.4311, you must identify the web coating/printing operation(s) for which you use the organic HAP overall control efficiency option or the oxidizer outlet organic HAP concentration option. If there were no deviations from the organic HAP overall control efficiency limitations, submit a statement that you were in compliance with the emission limitations during the reporting period because the organic HAP overall control efficiency for each compliance period was greater than or equal to the applicable organic HAP overall control efficiency in Table 1 to this subpart, and you achieved the operating limits required by § 63.4292 and the work practice standards required by § 63.4293 during each compliance period. If there were no deviations from the oxidizer outlet organic HAP concentration limit, submit a statement that you were in compliance with the oxidizer outlet organic HAP concentration limit, the efficiency of the capture system is 100 percent, and you achieved the operating limits required by § 63.4292 and the work practice standards required by § 63.4293 during each compliance period.

(g) During periods of startup, shutdown, or malfunction of the emission capture system, add-on control device, or web coating/printing operation that may affect emission capture or control device efficiency, you must operate in accordance with the startup, shutdown, and malfunction plan required by § 63.4300(c).

(h) Consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of startup, shutdown, or malfunction of the emission capture system, add-on control device, or web coating/printing operation that may affect emission capture or control device efficiency are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with the startup, shutdown, and malfunction plan. The Administrator will determine whether deviations that occur during a period of startup, shutdown, or malfunction are violations according to the provisions in § 63.6(e).

(i) [Reserved]

(j) You must maintain records as specified in §§ 63.4312 and 63.4313.

Performance Testing and Monitoring Requirements

§ 63.4360 What are the general requirements for performance tests?

(a) You must conduct each performance test required by §§ 63.4340 or 63.4350 according to the requirements in § 63.7(e)(1) and under the conditions in this section, unless you obtain a waiver of the performance test according to the provisions in § 63.7(h).

(1) *Representative web coating/printing or dyeing/finishing operation operating conditions.* You must conduct the performance test under representative operating conditions for the web coating/printing or dyeing/finishing operation. Operations during periods of startup, shutdown, or malfunction and during periods of nonoperation do not constitute representative conditions. You must record the process information that is necessary to document operating conditions during the test and explain why the conditions represent normal operation.

(2) *Representative emission capture system and add-on control device operating conditions.* You must conduct the performance test when the emission capture system and add-on control device are operating at a representative flow rate, and the add-on control device is operating at a representative inlet concentration. You must record information that is necessary to document emission capture system and add-on control device operating conditions during the test and explain why the conditions represent normal operation.

(b) You must conduct each performance test of an emission capture system according to the requirements in § 63.4361. You must conduct each performance test of an add-on control device according to the requirements in § 63.4362.

§ 63.4361 How do I determine the emission capture system efficiency?

You must use the procedures and test methods in this section to determine capture efficiency as part of the performance test required by §§ 63.4340 or 63.4350.

(a) *Assuming 100 percent capture efficiency.* You may assume the capture system efficiency is 100 percent if both of the conditions in paragraphs (a)(1) and (2) of this section are met.

(1) The capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and directs all the exhaust gases from the enclosure to an add-on control device.

(2) All regulated materials applied in the web coating/printing or dyeing/finishing operation are applied within the capture system; regulated material solvent flash-off, curing, and drying occurs within the capture system; and the removal or evaporation of cleaning materials from the web coating/printing operation surfaces they are applied to occurs within the capture system. For example, this criterion is not met if the web enters the open shop environment when moving between the application station and a curing oven.

(b) *Measuring capture efficiency.* If the capture system does not meet both of the criteria in paragraphs (a)(1) and (2) of this section, then you must use one of the three protocols described in paragraphs (c), (d), and (e) of this section to measure capture efficiency. The capture efficiency measurements use TVH capture efficiency as a

surrogate for organic HAP capture efficiency. For the protocols in paragraphs (c) and (d) of this section, the capture efficiency measurement must consist of three test runs. Each test run must be at least 3 hours duration or the length of a production run, up to 8 hours.

(c) *Liquid-to-uncaptured-gas protocol using a temporary total enclosure or building enclosure.* The liquid-to-uncaptured-gas protocol compares the mass of liquid TVH in regulated materials applied in the web coating/printing or dyeing/finishing operation to the mass of TVH emissions not captured by the emission capture system. Use a temporary total enclosure or a building enclosure and the procedures in paragraphs (c)(1) through (6) of this section to measure emission capture system efficiency using the liquid-to-uncaptured-gas protocol.

(1) Either use a building enclosure or construct an enclosure around the web coating/printing or dyeing/finishing operation where regulated materials are applied, and all areas where emissions from these applied regulated materials subsequently occur, such as flash-off, curing, and drying areas. The areas of the web coating/printing or dyeing/finishing operation where capture devices collect emissions for routing to an add-on control device, such as the entrance and exit areas of an oven or tenter frame, must also be inside the enclosure. The enclosure must meet the applicable definition of a temporary total enclosure or building enclosure in Method 204 of appendix M to 40 CFR part 51.

(2) Use Method 204A or 204F of appendix M to 40 CFR part 51 to determine the mass fraction of TVH liquid input from each regulated material used in the web coating/printing or dyeing/finishing operation during each capture efficiency test run. To make the determination, substitute TVH for each occurrence of the term volatile organic compounds (VOC) in the methods.

(3) Use Equation 1 of this section to calculate the total mass of TVH liquid input from all the regulated materials applied in the web coating/printing or dyeing/finishing operation during each capture efficiency test run.

$$TVH_{applied} = \sum_{i=1}^{n} \left(TVH_i\right)\left(M_i\right) \qquad \text{(Eq. 1)}$$

Where:

$TVH_{applied}$ = Mass of liquid TVH in regulated materials applied in the web coating/printing or dyeing/finishing operation during the capture efficiency test run, kg.

TVH_i = Mass fraction of TVH in regulated material, i, that is applied in the web coating/printing or dyeing/finishing operation during the capture efficiency test run, kg TVH per kg material.

M_i = Total mass of regulated material, i, applied in the web coating/printing or dyeing/finishing operation during the capture efficiency test run, kg.

n = Number of different regulated materials applied in the web coating/printing or dyeing/finishing operation during the capture efficiency test run.

(4) Use Method 204D or E of appendix M to 40 CFR part 51 to measure the total mass, kg, of TVH emissions that are not captured by the emission capture system; they are measured as they exit the temporary total enclosure or building enclosure during each capture efficiency test run. To make the measurement, substitute TVH for each occurrence of the term VOC in the methods.

(i) Use Method 204D if the enclosure is a temporary total enclosure.

(ii) Use Method 204E if the enclosure is a building enclosure. During the capture efficiency measurement, all organic compound-emitting operations inside the building enclosure, other than the web coating/printing or dyeing/finishing operation for which capture efficiency is being determined, must be shut down, but all fans and blowers must be operating normally.

(5) For each capture efficiency test run, determine the percent capture efficiency of the emission capture system using Equation 2 of this section:

$$CE = \frac{\left(TVH_{applied} - TVH_{uncaptured}\right)}{TVH_{applied}} \times 100 \qquad \text{(Eq. 2)}$$

Where:

CE = Capture efficiency of the emission capture system vented to the add-on control device, percent.

$TVH_{applied}$ = Total mass of TVH liquid input applied in the web coating/printing or dyeing/finishing operation during the capture efficiency test run, kg.

$TVH_{uncaptured}$ = Total mass of TVH that is not captured by the emission capture system and that exits from the temporary total enclosure or building enclosure during the capture efficiency test run, kg.

(6) Determine the capture efficiency of the emission capture system as the average of the capture efficiencies measured in the three test runs.

(d) *Gas-to-gas protocol using a temporary total enclosure or a building enclosure.* The gas-to-gas protocol compares the mass of TVH emissions captured by the emission capture system to the mass of TVH emissions not captured. Use a temporary total enclosure or a building enclosure and the procedures in paragraphs (d)(1) through (5) of this section to measure emission capture system efficiency using the gas-to-gas protocol.

(1) Either use a building enclosure or construct an enclosure around the web coating/printing or dyeing/finishing operation where regulated materials are applied, and all areas where emissions from these applied regulated materials subsequently occur, such as flash-off, curing, and drying areas. The areas of the web coating/printing or dyeing/finishing operation where capture devices collect emissions generated by the web coating/printing or dyeing/finishing operation for routing to an add-on control device, such as the entrance and exit areas of an oven or a tenter frame, must also be inside the enclosure. The enclosure must meet the applicable definition of a temporary total enclosure or building enclosure in Method 204 of appendix M to 40 CFR part 51.

(2) Use Method 204B or 204C of appendix M to 40 CFR part 51 to measure the total mass, kg, of TVH emissions captured by the emission capture system during each capture efficiency test run as measured at the inlet to the add-on control device. To make the measurement, substitute TVH for each occurrence of the term VOC in the methods.

(i) The sampling points for the Method 204B or 204C measurement must be upstream from the add-on control device and must represent total emissions routed from the capture system and entering the add-on control device.

(ii) If multiple emission streams from the capture system enter the add-on control device without a single common duct, then the emissions entering the add-on control device must be simultaneously measured in each duct and the total emissions entering the add-on control device must be determined.

(3) Use Method 204D or 204E of appendix M to 40 CFR part 51 to measure the total mass, kg, of TVH emissions that are not captured by the emission capture system; they are measured as they exit the temporary total enclosure or building enclosure during each capture efficiency test run. To make the measurement, substitute TVH for each occurrence of the term VOC in the methods.

(i) Use Method 204D if the enclosure is a temporary total enclosure.

(ii) Use Method 204E if the enclosure is a building enclosure. During the capture efficiency measurement, all organic compound-emitting operations inside the building enclosure, other than the web coating/printing or dyeing/finishing operation for which capture efficiency is being determined, must be shut down, but all fans and blowers must be operating normally.

(4) For each capture efficiency test run, determine the percent capture efficiency of the emission capture system using Equation 3 of this section:

$$CE = \frac{TVH_{captured}}{\left(TVH_{captured} + TVH_{uncaptured}\right)} \times 100 \qquad \text{(Eq. 3)}$$

Where:

CE = Capture efficiency of the emission capture system vented to the add-on control device, percent.

$TVH_{captured}$ = Total mass of TVH captured by the emission capture system as measured at the inlet to the add-on control device during the emission capture efficiency test run, kg.

$TVH_{uncaptured}$ = Total mass of TVH that is not captured by the emission capture system and that exits from the temporary total enclosure or building enclosure during the capture efficiency test run, kg.

(5) Determine the capture efficiency of the emission capture system as the average of the capture efficiencies measured in the three test runs.

(e) *Alternative capture efficiency protocol.* As an alternative to the procedures specified in paragraphs (c) and (d) of this section, you may determine capture efficiency using any other capture efficiency protocol and test methods that satisfy the criteria of either the DQO or LCL approach as described in appendix A to subpart KK of this part.

§ 63.4362 How do I determine the add-on control device emission destruction or removal efficiency?

You must use the procedures and test methods in this section to determine the add-on control device emission destruction or removal efficiency as part of the performance test required by §§ 63.4340 and 63.4350. You must conduct three test runs as specified in § 63.7(e)(3) and each test run must last at least 1 hour.

(a) For all types of add-on control devices, use the test methods as specified in paragraphs (a)(1) through (5) of this section.

(1) Use Method 1 or 1A of appendix A to 40 CFR part 60, as appropriate, to select sampling sites and velocity traverse points.

(2) Use Method 2, 2A, 2C, 2D, 2F, or 2G of appendix A to 40 CFR part 60, as appropriate, to measure gas volumetric flow rate.

(3) Use Method 3, 3A, or 3B of appendix A to 40 CFR part 60, as appropriate, for gas analysis to determine dry molecular weight. You may also use as an alternative to Method 3B, the manual method for measuring the oxygen, carbon dioxide, and carbon monoxide content of exhaust gas in ANSI/ASME, PTC 19.10–1981, ''Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus]'' (incorporated by reference, see § 63.14).

(4) Use Method 4 of appendix A to 40 CFR part 60 to determine stack gas moisture.

(5) Methods for determining gas volumetric flow rate, dry molecular weight, and stack gas moisture must be performed, as applicable, during each test run.

(b) Measure the volatile organic matter concentration as carbon at the inlet and outlet of the add-on control device simultaneously, using Method 25 or 25A of appendix A to 40 CFR part 60. If you are demonstrating compliance with the oxidizer outlet organic HAP concentration limit, only the outlet volatile organic matter concentration must be determined. The outlet volatile organic matter concentration is determined as the average of the three test runs.

(1) Use Method 25 if the add-on control device is an oxidizer and you expect the total gaseous organic concentration as carbon to be more than 50 parts per million (ppm) at the control device outlet.

(2) Use Method 25A if the add-on control device is an oxidizer and you expect the total gaseous organic concentration as carbon to be 50 ppm or less at the control device outlet. Method 25A must be used to demonstrate compliance with the oxidizer outlet organic HAP concentration limit.

(3) Use Method 25A if the add-on control device is not an oxidizer.

(c) If two or more add-on control devices are used for the same emission stream, then you must measure emissions at the outlet to the atmosphere of each device. For example, if one add-on control device is a concentrator with an outlet to the atmosphere for the high-volume, dilute stream that has been treated by the concentrator, and a second add-on control device is an oxidizer with an outlet to the atmosphere for the low-volume, concentrated stream that is treated with the oxidizer, you must measure emissions at the outlet of the oxidizer and the high volume dilute stream outlet of the concentrator.

(d) For each test run, determine the total gaseous organic emissions mass flow rates for the inlet and the outlet of the add-on control device, using Equation 1 of this section. If there is more than one inlet or outlet to the add-on control device, you must calculate the total gaseous organic mass flow rate using Equation 1 of this section for each

inlet and each outlet and then total all of the inlet emissions and total all of the outlet emissions:

$$M_f = Q_{sd} C_c [12] [0.0416] [10^{-6}] \qquad \text{(Eq. 1)}$$

Where:

M_f = Total gaseous organic emissions mass flow rate, kg/hour (h).

C_c = Concentration of organic compounds as carbon in the vent gas, as determined by Method 25 or Method 25A, ppmv, dry basis.

Q_{sd} = Volumetric flow rate of gases entering or exiting the add-on control device, as determined by Method 2, 2A, 2C, 2D, 2F, or 2G, dry standard cubic meters/hour (dscm/h).

0.0416 = Conversion factor for molar volume, kg-moles per cubic meter (mole/m^3) (@ 293 Kelvin (K) and 760 millimeters of mercury (mmHg)).

(e) For each test run, determine the add-on control device organic emissions destruction or removal efficiency using Equation 2 of this section.

$$DRE = \frac{M_{fi} - M_{fo}}{M_{fi}} \qquad \text{(Eq. 2)}$$

Where:

DRE = Organic emissions destruction or removal efficiency of the add-on control device, percent.

M_{fi} = Total gaseous organic emissions mass flow rate at the inlet(s) to the add-on control device, using Equation 1 of this section, kg/h.

M_{fo} = Total gaseous organic emissions mass flow rate at the outlet(s) of the add-on control device, using Equation 1 of this section, kg/h.

(f) Determine the emission destruction or removal efficiency of the add-on control device as the average of the efficiencies determined in the three test runs and calculated in Equation 2 of this section.

§ 63.4363 How do I establish the add-on control device operating limits during the performance test?

During the performance test required by §§ 63.4340 or 63.4350 and described in §§ 63.4360, 63.4361, and 63.4362, you must establish the operating limits required by § 63.4292 according to this section, unless you have received approval for alternative monitoring and operating limits under § 63.8(f) as specified in § 63.4292.

(a) *Thermal oxidizers.* If your add-on control device is a thermal oxidizer, establish the operating limits according to paragraphs (a)(1) and (2) of this section.

(1) During the performance test, you must monitor and record the temperature at least once every 15 minutes during each of the three test runs. You must monitor the temperature in the firebox of the thermal oxidizer or immediately downstream of the firebox before any substantial heat exchange occurs.

(2) Use the data collected during the performance test to calculate and record the average temperature maintained during the performance test. This average temperature is the minimum operating limit for your thermal oxidizer.

(b) *Catalytic oxidizers.* If your add-on control device is a catalytic oxidizer, establish the operating limits according to either paragraphs (b)(1) and (2) or paragraphs (b)(3) and (4) of this section.

(1) During the performance test, you must monitor and record the temperature at the inlet to the catalyst bed and the temperature difference across the catalyst bed at least once every 15 minutes during each of the three test runs.

(2) Use the data collected during the performance test to calculate and record the average temperature at the inlet to the catalyst bed and the average temperature difference across the catalyst bed maintained during the performance test. These are the minimum operating limits for your catalytic oxidizer.

(3) As an alternative to monitoring the temperature difference across the catalyst bed, you may monitor the temperature at the inlet to the catalyst bed and implement a site-specific inspection and maintenance plan for your catalytic oxidizer as specified in paragraph (b)(4) of this section. During the performance test, you must monitor and record the temperature just before the catalyst bed at least once every 15 minutes during each of the three test runs. Use the data collected during the performance test to calculate and record the average temperature just before the catalyst bed during the performance test. This is the minimum operating limit for your catalytic oxidizer.

(4) You must develop and implement an inspection and maintenance plan for your catalytic oxidizer(s) for which you elect to monitor according to paragraph (b)(3) of this section. The plan must address, at a minimum, the elements specified in paragraphs (b)(4)(i) through (iii) of this section.

(i) Annual sampling and analysis of the catalyst activity (*i.e.*, conversion efficiency) following the manufacturer's or catalyst supplier's recommended procedures.

(ii) Monthly inspection of the oxidizer system, including the burner assembly and fuel supply lines for problems and, as necessary, adjust the equipment to assure proper air-to-fuel mixtures.

(iii) Annual internal and monthly external visual inspection of the catalyst bed to check for channeling, abrasion, and settling. If problems are found, you must take corrective action consistent with the manufacturer's recommendations and conduct a new performance test to determine destruction efficiency according to § 63.4362.

§ 63.4364 What are the requirements for CPMS installation, operation, and maintenance?

(a) *General.* If you are using a control device to comply with the emission standards in § 63.4290, you must install, operate, and maintain each CPMS specified in paragraphs (c) and (d) and (e) of this section according to the requirements in paragraphs (a)(1) through (8) of this section. You must install, operate, and maintain each CPMS specified in paragraph (b) of this section according to paragraphs (a)(5) through (7) of this section.

(1) Each CPMS must complete a minimum of one cycle of operation for each successive 15-minute period. You must have a minimum of four equally spaced successive cycles of CPMS operation to have a valid hour of data.

(2) You must have valid data from at least 90 percent of the hours during which the process operated.

(3) You must determine the hourly average of all recorded readings according to paragraphs (a)(3)(i) and (ii) of this section.

(i) To calculate a valid hourly value, you must have at least three of four equally spaced data values from that hour from a continuous monitoring system (CMS) that is not out-of-control.

(ii) Provided all of the readings recorded in accordance with paragraph (a)(3) of this section clearly demonstrate continuous compliance with the standard that applies to you, then you

are not required to determine the hourly average of all recorded readings.

(4) You must determine the rolling 3-hour average of all recorded readings for each operating period. To calculate the average for each 3-hour averaging period, you must have at least two of three of the hourly averages for that period using only average values that are based on valid data (*i.e.*, not from out-of-control periods).

(5) You must record the results of each inspection, calibration, and validation check of the CPMS.

(6) At all times, you must maintain the monitoring system in proper working order including, but not limited to, maintaining necessary parts for routine repairs of the monitoring equipment.

(7) Except for monitoring malfunctions, associated repairs, or required quality assurance or control activities (including calibration checks or required zero and span adjustments), you must conduct all monitoring at all times that the unit is operating. Data recorded during monitoring malfunctions, associated repairs, out-of-control periods, or required quality assurance or control activities shall not be used for purposes of calculating the emissions concentrations and percent reductions specified in Table 1 to this subpart. You must use all the valid data collected during all other periods in assessing compliance of the control device and associated control system. A monitoring malfunction is any sudden, infrequent, not reasonably preventable failure of the monitoring system to provide valid data. Monitoring failures that are caused in part by poor maintenance or careless operation are not malfunctions.

(8) Any averaging period for which you do not have valid monitoring data and such data are required constitutes a deviation, and you must notify the Administrator in accordance with § 63.4311(a).

(b) *Capture system bypass line.* You must meet the requirements of paragraphs (a)(5) through (6) and (b)(1) and (2) of this section for each emission capture system that contains bypass lines that could divert emissions away from the add-on control device to the atmosphere.

(1) You must monitor or secure the valve or closure mechanism controlling the bypass line in a nondiverting position in such a way that the valve or closure mechanism cannot be opened without creating a record that the valve was opened. The method used to monitor or secure the valve or closure mechanism must meet one of the requirements specified in paragraphs (b)(1)(i) through (iv) of this section.

(i) *Flow control position indicator.* Install, calibrate, maintain, and operate according to the manufacturer's specifications a flow control position indicator that takes a reading at least once every 15 minutes and provides a record indicating whether the emissions are directed to the add-on control device or diverted from the add-on control device. The time of occurrence and flow control position must be recorded, as well as every time the flow direction is changed. The flow control position indicator must be installed at the entrance to any bypass line that could divert the emissions away from the add-on control device to the atmosphere.

(ii) *Car-seal or lock-and-key valve closures.* Secure any bypass line valve in the closed position with a car-seal or a lock-and-key type configuration. You must visually inspect the seal or closure mechanism at least once every month to ensure that the valve is maintained in the closed position, and the emissions are not diverted away from the add-on control device to the atmosphere.

(iii) *Valve closure continuous monitoring.* Ensure that any bypass line valve is in the closed (non-diverting) position through monitoring of valve position at least once every 15 minutes. You must inspect the monitoring system at least once every month to verify that the monitor will indicate valve position.

(iv) *Automatic shutdown system.* Use an automatic shutdown system in which the web coating/printing or dyeing/finishing operation is stopped when flow is diverted by the bypass line away from the add-on control device to the atmosphere when the web coating/printing or dyeing/finishing operation is running. You must inspect the automatic shutdown system at least once every month to verify that it will detect diversions of flow and shutdown the web coating/printing or dyeing/finishing operation.

(2) If any bypass line is opened, you must include a description of why the bypass line was opened and the length of time it remained open in the semiannual compliance reports required in § 63.4311.

(c) *Oxidizers.* If you are using an oxidizer to comply with the emission standards, you must comply with paragraphs (c)(i) through (iii) of this section.

(i) Install, calibrate, maintain, and operate temperature monitoring equipment according to the manufacturer's specifications. The calibration of the chart recorder, data logger, or temperature indicator must be verified every 3 months or the chart recorder, data logger, or temperature indicator must be replaced.

(ii) For an oxidizer other than a catalytic oxidizer, install, calibrate, operate, and maintain a temperature monitoring device equipped with a continuous recorder. The device must have an accuracy of ±1 percent of the temperature being monitored in degrees Celsius, or ±1°Celsius, whichever is greater. The thermocouple or temperature sensor must be installed in the combustion chamber at a location in the combustion zone.

(iii) For a catalytic oxidizer, install, calibrate, operate, and maintain a temperature monitoring device equipped with a continuous recorder. The device must be capable of monitoring temperature with an accuracy of ±1 percent of the temperature being monitored in degrees Celsius or ± 1 degree Celsius, whichever is greater. The thermocouple or temperature sensor must be installed in the vent stream at the nearest feasible point to the inlet and outlet of the catalyst bed. Calculate the temperature rise across the catalyst.

(d) *Other types of control devices.* If you use a control device other than an oxidizer or wish to monitor an alternative parameter and comply with a different operating limit, you must apply to the Administrator for approval of an alternative monitoring method under § 63.8(f).

(e) *Capture system monitoring.* If you are complying with the emission standards in § 63.4290 through the use of a capture system and control device, you must develop a site-specific monitoring plan containing the information specified in paragraphs (e)(1) and (2) of this section for these capture systems. You must monitor the capture system in accordance with paragraph (e)(3) of this section. You must make the monitoring plan available for inspection by the permitting authority upon request.

(1) The monitoring plan must:

(i) Identify the operating parameter to be monitored to ensure that the capture efficiency determined during the initial compliance test is maintained; and

(ii) Explain why this parameter is appropriate for demonstrating ongoing compliance; and

(iii) Identify the specific monitoring procedures.

(2) The monitoring plan must specify the operating parameter value or range of values that demonstrate compliance with the emission standards in § 63.4290. The specified operating parameter value or range of values must represent the conditions present when

the capture system is being properly operated and maintained.

(3) You must conduct all capture system monitoring in accordance with the plan.

(4) Any deviation from the operating parameter value or range of values which are monitored according to the plan will be considered a deviation from the operating limit.

(5) You must review and update the capture system monitoring plan at least annually.

Other Requirements and Information

§ 63.4370 Who implements and enforces this subpart?

(a) This subpart can be implemented and enforced by us, the U.S. EPA, or a delegated authority such as your State, local, or tribal agency. If the Administrator has delegated authority to your State, local, or tribal agency, then that agency (as well as the U.S. EPA), has the authority to implement and enforce this subpart. You should contact your EPA Regional Office to find out if implementation and enforcement of this subpart is delegated to your State, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or tribal agency under subpart E of this part, the authorities contained in paragraph (c) of this section are retained by the Administrator and are not transferred to the State, local, or tribal agency.

(c) The authorities that will not be delegated to State, local, or tribal agencies are listed in paragraphs (c)(1) through (4) of this section:

(1) Approval of alternatives to the work practice standards in § 63.4293 under § 63.6(g).

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f) and as defined in § 63.90.

(3) Approval of major alternatives to monitoring under § 63.8(f) and as defined in § 63.90.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f) and as defined in § 63.90.

§ 63.4371 What definitions apply to this subpart?

Terms used in this subpart are defined in the CAA, in 40 CFR 63.2, and in this section as follows:

Add-on control means an air pollution control device, such as a thermal oxidizer or carbon adsorber, that reduces pollution in an air stream by destruction or removal before discharge to the atmosphere.

As-applied means the condition of a coating at the time of application to a substrate, including any added solvent.

As purchased means the condition of a coating, printing, slashing, dyeing, or finishing material as delivered to the affected source, before alteration.

Capture device means a hood, enclosure, room, floor sweep, or other means of containing or collecting emissions and directing those emissions into an add-on air pollution control device.

Capture efficiency means the portion (expressed as a percentage) of the pollutants from an emission source that is delivered to an add-on control device.

Capture system means one or more capture devices intended to collect emissions generated by a web coating/printing or dyeing/finishing operation in the use of regulated materials, both at the point of application and at subsequent points where emissions from the regulated materials occur, such as flashoff, drying, or curing. As used in this subpart, multiple capture devices that collect emissions generated by a web coating/printing or dyeing/finishing operation are considered a single capture system.

Cleaning material means a solvent used to remove contaminants and other materials, such as dirt, grease, or oil, from a textile before a web coating/printing operation (surface preparation) or from equipment associated with the web coating/ printing operation, such as tanks, rollers, rotary screens, and knife or wiper blades. Thus, it includes any cleaning material used in the web coating and printing subcategory for surface preparation of substrates or process operation equipment cleaning or both with the exception of cleaning material applied to the substrate using handheld, non-refillable aerosol containers.

Coating means the application of a semi-liquid coating material to one or both sides of a textile web substrate. Once the coating material is dried (and cured, if necessary), it bonds with the textile to form a continuous solid film for decorative, protective, or functional purposes. Coating does not include finishing where the fiber is impregnated with a chemical or resin to impart certain properties, but a solid film is not formed.

Coating material means an elastomer, polymer, or prepolymer material applied as a thin layer to a textile web. Such materials include, but are not limited to, coatings, sealants, inks, and adhesives. Decorative, protective, or functional materials that consist only of acids, bases, or any combination of these substances are not considered coating material for the purposes of this subpart. Thinning materials also are not included in this definition of coating materials, but are accounted for separately.

Coating operation means equipment used to apply cleaning materials to a web substrate to prepare it for coating material application (surface preparation), to apply coating material to a web substrate (coating application) and to dry or cure the coating material after application by exposure to heat or radiation (coating drying or curing), or to clean coating operation equipment (equipment cleaning). A single coating operation may include any combination of these types of equipment, but always includes at least the point at which a coating or cleaning material is applied and all subsequent points in the affected source where organic HAP emissions from that coating or cleaning material occur. There may be multiple coating operations in an affected source. Coating material application with handheld, non-refillable aerosol containers, touch-up markers, or marking pens is not a coating operation for the purposes of this subpart. Polyurethane foam carpet backing operations are not coating operations for the purposes of this subpart.

Container means any portable device in which a material is stored, conveyed, treated, disposed of, or otherwise handled.

Continuous parameter monitoring system means the total equipment that may be required to meet the data acquisition and availability requirements of this subpart, used to sample, condition (if applicable), analyze, and provide a record of coating or printing operation, or capture system, or add-on control device parameters.

Controlled web coating/printing or dyeing/finishing operation means a web coating/printing or dyeing/finishing operation from which some or all of the organic HAP emissions are routed through an emission capture system and add-on control device.

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limit, or operating limit, or work practice standard;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limit, or operating limit, or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of

whether or not such failure is permitted by this subpart.

Dyeing means the process of applying color to the whole body of a textile substrate with either natural or synthetic dyes. Dyes are applied to yarn, fiber, cord, or fabric in aqueous solutions and dried before or after finishing, depending on the process. Continuous dyeing processes include, but are not limited to thermosol, pad/steam, pad/dry, and rope range dyeing. Batch dyeing processes include, but are not limited to, jet, beck, stock, yarn, kier, beam, pad, package and skein dyeing.

Dyeing materials means the purchased dyes and dyeing auxiliaries that are used in the dyeing process. The dyes are the substances that add color to textiles through incorporation into the fiber by chemical reaction, absorption or dispersion. Dyeing auxiliaries are various substances that can be added to the dyebath to aid dyeing. Dyeing auxiliaries may be necessary to transfer the dye from the dyebath to the fiber or they may provide improvements in the dyeing process or characteristics of the dyed fiber.

Dyeing operation means the collection of equipment used to dye a textile substrate and includes equipment used for dye application, dye fixation, and textile substrate rinsing and drying. A single dyeing operation may include any combination of these types of equipment, but always includes at least the point at which a dyeing material is applied and all subsequent points in the affected source where organic HAP emissions from that dyeing material occur. There may be multiple dyeing operations in an affected source. Dyeing material application with handheld, non-refillable aerosol containers, touch-up markers, brushes, or marking pens is not a dyeing operation for the purposes of this subpart.

Emission limitation means an emission limit, operating limit, or work practice standard.

Enclosure means a structure that surrounds a source of emissions and captures and directs the emissions to an add-on control device.

Fabric means any woven, knitted, plaited, braided, felted, or non-woven material made of filaments, fibers, or yarns including thread. This term includes material made of fiberglass, natural fibers, synthetic fibers, or composite.

Finishing means the chemical treatment of a textile (*e.g.*, with resins, softeners, stain resist or soil release agents, water repellants, flame retardants, antistatic agents, or hand builders) that improves the appearance and/or usefulness of the textile substrate.

Finishing materials means the purchased substances (including auxiliaries added to the finish to improve the finishing process or the characteristics of the finished textile) that are applied individually or as mixtures to textile substrates to impart desired properties.

Finishing operations means the collection of equipment used to finish a textile substrate including chemical finish applicator(s), flashoff area(s) and drying or curing oven(s).

Laminated fabric means fabric composed of a high-strength reinforcing base fabric between two plies of flexible thermoplastic film. Two or more fabrics or textiles or a fabric and a paper substrate may be bonded with an adhesive to form a laminate. The bonding of a fabric substrate to paper is not subject to the requirements of this subpart.

Manufacturer's formulation data means data on a material (such as a coating, printing, slashing, dyeing and finishing) that are supplied by the material manufacturer based on knowledge of the ingredients used to manufacture that material, rather than based on testing of the material. Manufacturer's formulation data may include, but are not limited to, information on density, organic HAP content, and coating, printing, dyeing, slashing, finishing, thinning, or cleaning material content.

Mass fraction of organic HAP means the ratio of the mass of organic HAP to the mass of a material in which it is contained; kg of organic HAP per kg of material.

Month means a calendar month or a pre-specified period of 28 days to 35 days to allow for flexibility in recordkeeping when data are based on a business accounting period.

No organic HAP means no organic HAP is present at 0.1 percent by mass or more for OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) and at 1.0 percent by mass or more for other compounds. The organic HAP content of a regulated material is determined according to § 63.4321(e)(1).

Operating scenario means for a dyeing/finishing process operation or group of process operations, the combination of operating conditions (including but not limited to, type of substrate, type and mass fraction of organic HAP in dyeing/finishing materials applied, and the process operation temperature and pressure) affecting the fraction of organic HAP applied in dyeing and finishing operations discharged to wastewater. For example, a dyeing process operation run at atmospheric pressure would be a different operating scenario from the same dyeing process operation run under pressure.

Organic HAP content means the mass of organic HAP per mass of solids for a coating or printing material calculated using Equation 1 of § 63.4321. The organic HAP content is determined for the coating or printing material as purchased.

Organic HAP overall control efficiency means the total efficiency of a control system, determined either by:

(1) The product of the capture efficiency as determined in accordance with the requirements of § 63.4361 and the control device organic emissions destruction or removal efficiency determined in accordance with the requirements of § 63.4362; or

(2) A liquid-liquid material balance in accordance with the requirements of § 63.4341(e)(5) or (f)(5) or § 63.4351(d)(5).

Permanent total enclosure (PTE) means a permanently installed enclosure that meets the criteria of Method 204 of appendix M, 40 CFR part 51, for a PTE and that directs all the exhaust gases from the enclosure to an add-on control device.

Point of determination means each point where process wastewater exits the dyeing/finishing process unit.

Printing means the application of color and patterns to textiles, usually in the form of a paste, using a variety of techniques including, but not limited to roller, rotary screen, and ink jet printing. After application of the printing material, the textile usually is treated with steam, heat, or chemicals to fix the color.

Printing material means the purchased substances, usually including gums or thickeners, dyes and appropriate chemicals such as defoamers and resins that are mixed to produce the print pastes applied to textile substrates as patterns and colors.

Printing operation means equipment used to apply cleaning materials to a web substrate to prepare it for printing material application (surface preparation), to apply printing material to one or both sides of a web substrate (printing application) and to dry or cure the printing material after application by exposure to heat or radiation (printing material drying or curing), or to clean printing operation equipment (equipment cleaning). A single printing operation may include any combination of these types of equipment, but always includes at least the point at which a printing or cleaning material is applied and all subsequent points in the affected

source where organic HAP emissions from that printing or cleaning material occur. There may be multiple printing operations in an affected source.

Publically owned treatment works or *POTW* means any device or system used in the treatment (including recycling and reclamation) of municipal sewage or industrial wastes of a liquid nature which is owned by a ''State'' or ''municipality'' (as defined by section 502(4) of the CWA). This definition includes sewers, pipes or other conveyances only if they convey wastewater to a POTW providing treatment.

Regulated materials means the organic-containing materials that are used in the three printing, coating, and dyeing subcategories defined in § 63.4281(a). Organic-HAP containing regulated materials are the source of the organic HAP emissions limited by the requirements of this subpart. The specific regulated materials for each subcategory are defined in § 63.4282.

Research or laboratory operation means an operation whose primary purpose is for research and development of new processes and products that is conducted under the close supervision of technically trained personnel and is not engaged in the manufacture of final or intermediate products for commercial purposes, except in a *de minimis* manner.

Responsible official means responsible official as defined in 40 CFR 70.2.

Slashing means the application of a chemical sizing solution to warp yarns prior to weaving to protect against snagging or abrasion that could occur during weaving.

Slashing materials, also known as sizing, means the purchased compounds that are applied to warp yarns prior to weaving. Starch, gelatin, oil, wax, and manufactured polymers such as polyvinyl alcohol, polystyrene, polyacrylic acid and polyacetates are used as sizing compounds.

Slashing operation means the equipment used to mix and prepare size for application and the slasher, which is the equipment used to apply and dry size on warp yarn.

Solids means the nonvolatile portion of the coating and printing materials that makes up the dry film on a coated substrate and the pattern or color on a printed substrate.

Startup, initial means the first time equipment is brought online in a facility.

Surface preparation means chemical treatment of part or all of a substrate to prepare it for coating or printing material application.

Temporary total enclosure means an enclosure constructed for the purpose of measuring the capture efficiency of pollutants emitted from a given source as defined in Method 204 of appendix M, 40 CFR part 51.

Textile means any one of the following:

(1) Staple fibers and filaments suitable for conversion to or use as yarns, or for the preparation of woven, knit, or nonwoven fabrics;

(2) Yarns made from natural or manufactured fibers;

(3) Fabrics and other manufactured products made from staple fibers and filaments and from yarn; and

(4) Garments and other articles fabricated from fibers, yarns, or fabrics.

Thinning material means an organic solvent that is added to a coating or printing material after the coating or printing material is received from the supplier.

Total volatile hydrocarbon (TVH) means the total amount of nonaqueous volatile organic material determined according to Methods 204A through 204C of appendix M to 40 CFR part 51 and substituting the term TVH each place in the methods where the term VOC is used. The TVH includes both VOC and non-VOC.

Uncontrolled web coating/printing or dyeing/finishing operation means acoating/printing or dyeing/finishing operation from which none of the organic HAP emissions are routed through an emission capture system and add-on control device.

Volatile organic compounds (VOC) means any compounds defined as VOC in 40 CFR 51.100(s).

Wastewater means water that is generated in a web coating, web printing, slashing, dyeing or finishing operation and is collected, stored, or treated prior to being discarded or discharged.

Web means a continuous textile substrate which is flexible enough to be wound or unwound as rolls.

Tables to Subpart OOOO of Part 63

If you are required to comply with emission limitations in accordance with §§ 63.4290 and 63.4291, you must comply with the applicable emission limits in the following table:

TABLE 1 TO SUBPART OOOO OF PART 63.—EMISSION LIMITS FOR NEW OR RECONSTRUCTED AND EXISTING AFFECTED SOURCES IN THE PRINTING, COATING AND DYEING OF FABRICS AND OTHER TEXTILES SOURCE CATEGORY

If your affected source is a . . .	And it conducts . . .	Then this is the organic HAP emission limit for each compliance period . . .
1. New or reconstructed coating and printing affected source.	Coating operations only, *or* Printing operations only, *or* Both coating and printing operations.	You may choose any one of the following limits: Reduce organic HAP emissions to the atmosphere by achieving at least a 98 percent organic HAP overall control efficiency; Limit organic HAP emissions to the atmosphere to no more than 0.08 kg of organic HAP per kg of solids applied; or If you use an oxidizer to control organic HAP emissions, operate the oxidizer such that an outlet organic HAP concentration of no greater than 20 ppmv on a dry basis is achieved and the efficiency of the capture system is 100 percent.

TABLE 1 TO SUBPART OOOO OF PART 63.—EMISSION LIMITS FOR NEW OR RECONSTRUCTED AND EXISTING AFFECTED SOURCES IN THE PRINTING, COATING AND DYEING OF FABRICS AND OTHER TEXTILES SOURCE CATEGORY—Continued

If your affected source is a . . .	And it conducts . . .	Then this is the organic HAP emission limit for each compliance period . . .
2. Existing coating and printing affected source	Coating operations only, *or* Printing operations only, *or* Both coating and printing operations.	You may choose any one of the following limits: Reduce organic HAP emissions to the atmosphere by achieving at least a 97 percent organic HAP overall control efficiency; Limit organic HAP emissions to the atmosphere to no more than 0.12 kg of organic HAP per kg of solids applied; or If you use an oxidizer to control organic HAP emissions, operate the oxidizer such that an outlet organic HAP concentration of no greater than 20 ppmv on a dry basis is achieved and the efficiency of the capture system is 100 percent.
3. New, reconstructed or existing dyeing finishing affected source.	a. Dyeing operations only	You must limit organic HAP emissions to the atmosphere to no more than 0.016 kg of organic HAP per kg of dyeing materials applied.
	b. Finishing operations only	You must limit organic HAP emissions to the atmosphere to no more than 0.0003 kg of organic HAP per kg of finishing materials applied.
	c. Both dyeing and finishing operations	You must limit organic HAP emissions to the atmosphere to no more than 0.016 kg of organic HAP per kg of dyeing and finishing materials applied.
4. New, reconstructed or existing slashing affected source.	Slashing operations only	You must limit organic HAP emissions to the atmosphere to no more than zero kg organic HAP per kg of slashing materials as determined according to § 63.4321(e)(1)(iv) of this subpart.

If you are required to comply with the operating limits by § 63.4292, you must comply with the applicable operating limits in the following table:

TABLE 2 TO SUBPART OOOO OF PART 63.—OPERATING LIMITS IF USING ADD-ON CONTROL DEVICES AND CAPTURE SYSTEM

For the following device . . .	You must meet the following operating limit . . .	And you must demonstrate continuous compliance with the operating limit by . . .
1. Thermal oxidizer	a. The average temperature in any 3-hour block period must not fall below the temperature limit established according to § 63.4363(a)	i. Collecting the temperature data according to § 63.4364(c); ii. Reducing the data to 3-hour block averages; and iii. Maintaining the 3-hour block average temperature at or above the temperature limit.
2. Catalytic oxidizer	a. The average temperature measured at the inlet to the catalyst bed in any 3-hour block period must not fall below the limit established according to § 63.4363(b); and either	i. Collecting the temperature data according to § 63.4364(c); ii. reducing the data to 3-hour block averages; and iii. maintaining the 3-hour block average catalyst bed inlet temparature at or above temperature limit.
	b. Ensure that the average temperature difference across the catalyst bed in any 3-hour block period does not fall below the temperature difference limit established according to § 63.4363(b)(2); or	Collecting the temperature data according to § 63.4364(c), reducing the data to 3-hour block averages, and maintaining the 3-hour block average temperature difference at or above the temperature difference limit.

TABLE 2 TO SUBPART OOOO OF PART 63.—OPERATING LIMITS IF USING ADD-ON CONTROL DEVICES AND CAPTURE SYSTEM—Continued

For the following device . . .	You must meet the following operating limit . . .	And you must demonstrate continuous compliance with the operating limit by . . .
	c. Develop and implement an inspection and maintenance plan according to § 63.4363(b)(4).	Maintaining an up-to-date inspection and maintenance plan, records of annual catalyst activity checks, records of monthly inspections of the oxidizer system, and records of the annual internal inspections of the catalyst bed. If a problem is discovered during a monthly or annual inspection required by § 63.4363(b)(4), you must take corrective action as soon as practicable consistent with the manufacturer's recommendations.
3. Emission capture system	Submit monitoring plan to the Administrator that identifies operating parameters to be monitored according to § 63.4364(e).	Conduct monitoring according to the plan (§ 63.4364(e)(3)).

You must comply with the applicable General Provisions requirements according to the following table:

TABLE 3 TO SUBPART OOOO OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART OOOO

Citation	Subject	Applicable to subpart OOOO	Explanation
§ 63.1(a)(1)–(12)	General Applicability	Yes.	
§ 63.1(b)(1)–(3)	Initial Applicability Determination	Yes	Applicability to subpart OOOO is also specified in § 63.4281.
§ 63.1(c)(1)	Applicability After Standard Established	Yes.	
§ 63.1(c)(2)–(3)	Applicability of Permit Program for Area Sources.	No	Area sources are not subject to subpart OOOO.
§ 63.1(c)(4)–(5)	Extensions and Notifications	Yes.	
§ 63.1(e)	Applicability of Permit Program Before Relevant Standard is Set.	Yes.	
§ 63.2	Definitions	Yes	Additional definitions are specified in § 63.4371.
§ 63.3(a)–(c)	Units and Abbreviations	Yes.	
§ 63.4(a)(1)–(5)	Prohibited Activities	Yes.	
§ 63.4(b)–(c)	Circumvention/Severability	Yes.	
§ 63.5(a)	Construction/Reconstruction	Yes.	
§ 63.5(b)(1)–(6)	Requirements for Existing, Newly Constructed, and Reconstructed Sources.	Yes.	
§ 63.5(d)	Application for Approval of Construction/Reconstruction.	Yes.	
§ 63.5(e)	Approval of Construction/Reconstruction	Yes.	
§ 63.5(f)	Approval of Construction/Reconstruction Based on Prior State Review.	Yes.	
§ 63.6(a)	Compliance With Standards and Maintenance Requirements—Applicability.	Yes.	
§ 63.6(b)(1)–(7)	Compliance Dates for New and Reconstructed Sources.	Yes	Section 63.4283 specifies the compliance dates.

TABLE 3 TO SUBPART OOOO OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART OOOO—Continued

Citation	Subject	Applicable to subpart OOOO	Explanation
§ 63.6(c)(1)–(5)	Compliance Dates for Existing Sources	Yes	Section 63.4283 specifies the compliance dates.
§ 63.6(e)(1)–(2)	Operation and Maintenance	Yes.	
§ 63.6(e)(3)	Startup, Shutdown, and Malfunction Plan	Yes	Only sources using an add-on control device to comply with the standards must complete startup, shutdown, and malfunction plans.
§ 63.6(f)(1)	Compliance Except During Startup, Shutdown, and Malfunction.	Yes	Applies only to sources using an add-on control device to comply with the standards.
§ 63.6(f)(2)–(3)	Methods for Determining Compliance	Yes.	
§ 63.6(g)(1)–(3)	Use of an Alternative Standard	Yes.	
§ 63.6(h)	Compliance With Opacity/Visible Emission Standards.	No	Subpart OOOO does not establish opacity standards and does not require continuous opacity monitoring systems (COMS).
§ 63.6(i)(1)–(16)	Extension of Compliance	Yes.	
§ 63.6(j)	Presidential Compliance Exemption	Yes.	
§ 63.7(a)(1)	Performance Test Requirements—Applicability	Yes	Applies to all affected sources. Additional requirements for performance testing are specified in §§ 63.4360, 63.4361, and 63.4362.
§ 63.7(a)(2)	Performance Test Requirements—Dates	Yes	Applies only to performance tests for capture system and control device efficiency at sources using these to comply with the standard.
§ 63.7(a)(3)	Performance Tests Required by the Administrator.	Yes.	
§ 63.7(b)–(e)	Performance Test Requirements—Notification, Quality Assurance, Facilities Necessary for Safe Testing, Conditions During Test.	Yes	Applies only to performance tests for capture system and control device efficiency at sources using these to comply with the standard.
§ 63.7(f)	Performance Test Requirements—Use of Alternative Test Method.	Yes	Applies to all test methods except those used to determine capture system efficiency.
§ 63.7(g)–(h)	Performance Test Requirements—Data Analysis, Recordkeeping, Waiver of Test.	Yes	Applies only to performance tests for capture system and add-on control device efficiency at sources using these to comply with the standards.
§ 63.8(a)(1)–(3)	Monitoring Requirements—Applicability	Yes	Applies only to monitoring of capture system and add-on control device efficiency at sources using these to comply with the standards. Additional requirements for monitoring are specified in § 63.4364.
§ 63.8(a)(4)	Additional Monitoring Requirements	No	Subpart OOOO does not have monitoring requirements for flares.
§ 63.8(b)	Conduct of Monitoring	Yes.	
§ 63.8(c)(1)–(3)	Continuous Monitoring Systems (CMS) Operation and Maintenance.	Yes	Applies only to monitoring of capture system and add-on control device efficiency at sources using these to comply with the standards. Additional requirements for CMS operations and maintenance are specified in § 63.4364.
§ 63.8(c)(4)	CMS	No	Section 63.4364 specifies the requirements for the operation of CMS for capture systems and add-on control devices at sources using these to comply.

TABLE 3 TO SUBPART OOOO OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART OOOO—Continued

Citation	Subject	Applicable to subpart OOOO	Explanation
§ 63.8(c)(5)	COMS	No	Subpart OOOO does not have opacity or visible emission standards.
§ 63.8(c)(6)	CMS Requirements	No	Section 63.4364 specifies the requirements for monitoring systems for capture systems and add-on control devices at sources using these to comply.
§ 63.8(c)(7)–(8)	CMS Out of Control Periods and Reporting	Yes.	
§ 63.8(d)—(e)	Quality Control Program and CMS Performance Evaluation.	No	Subpart OOOO does not require the use of continuous emissions monitoring systems.
§ 63.8(f)(1)–(5)	Use of an Alternative Monitoring Method	Yes.	
§ 63.8(f)(6)	Alternative to Relative Accuracy Test	No	Subpart OOOO does not require the use of continuous emissions monitoring systems.
§ 63.8(g)(1)–(5)	Data Reduction	No	Sections 63.4342 and 63.4352 specify monitoring data reduction.
§ 63.9(a)	Applicability and General Information	Yes.	
§ 63.9(b)	Initial Notifications	No	Subpart OOOO provides 1 year for an existing source to submit an initial notification.
§ 63.9(c)	Request for Extension of Compliance	Yes.	
§ 63.9(d)	Notification that Source is Subject to Special Compliance Requirements.	Yes.	
§ 63.9(e)	Notification of Performance Test	Yes	Applies only to capture system and add-on control device performance tests at sources using these to comply with the standards.
§ 63.9(f)	Notification of Visible Emissions/Opacity Test	No	Subpart OOOO does not have opacity or visible emission standards.
§ 63.9(g)(1)–(3)	Additional Notifications When Using CMS	No	Subpart OOOO does not require the use of continuous emissions monitoring systems.
§ 63.9(h)	Notification of Compliance Status	Yes	Section 63.4310 specifies the dates for submitting the notification of compliance status.
§ 63.9(i)	Adjustment of Submittal Deadlines	Yes.	
§ 63.9(j)	Change in Previous Information	Yes.	
§ 63.10(a)	Recordkeeping/Reporting—Applicability and General Information	Yes.	
§ 63.10(b)(1)	General Recordkeeping Requirements	Yes	Additional Requirements are specified in §§ 63.4312 and 63.4313.
§ 63.10(b)(2)(i)–(v)	Recordkeeping Relevant to Startup, Shutdown, and Malfunction Periods and CMS.	Yes	Requirements for Startup, Shutdown, and Malfunction records only apply to add-on control devices used to comply with the standards.
§ 63.10(b)(2)(vi)–(xi)		Yes.	
§ 63.10(b)(2)(xii)	Records	Yes.	
§ 63.10(b)(2)(xiii)		No	Subpart OOOO does not require the use of continuous emissions monitoring systems.
§ 63.10(b)(2)(xiv)		Yes.	
§ 63.10(b)(3)	Recordkeeping Requirements for Applicability Determinations.	Yes.	

TABLE 3 TO SUBPART OOOO OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART OOOO—Continued

Citation	Subject	Applicable to subpart OOOO	Explanation
§ 63.10(c)(1)–(6)	Additional Recordkeeping Requirements for Sources with CMS.	Yes.	
§ 63.10(c)(7)–(8)		No	The same records are required in § 63.4311(a)(7).
§ 63.10(c)(9)–(15)		Yes.	
§ 63.10(d)(1)	General Reporting Requirements	Yes	Addtional requirements are specified in § 63.4311.
§ 63.10(d)(2)	Report of Performance Test Results	Yes	Additional requirements are specified in § 63.4311(b).
§ 63.10(d)(3)	Reporting Opacity or Visible Emissions Observations.	No	Subpart OOOO does not require opacity or visible emissions observations.
§ 63.10(d)(4)	Progress Reports for Sources With Compliance Extensions.	Yes.	
§ 63.10(d)(5)	Startup, Shutdown, and Malfunction Reports	Yes	Applies only to add-on control devices at sources using these to comply with the standards.
§ 63.10(e)(1)–(2)	Additional CMS Reports	No	Subpart OOOO does not require the use of continuous emissions monitoring systems.
§ 63.10(e)(3)	Excess Emissions/CMS Performance Reports	No	Section 63.4311(a) specifies the contents of periodic compliance reports.
§ 63.10(e)(4)	COMS Data Reports	No	Subpart OOOO does not specify requirements for opacity or COMS.
§ 63.10(f)	Recordkeeping/Reporting Waiver	Yes.	
§ 63.11	Control Device Requirements/Flares	No	Subpart OOOO does not specify use of flares for compliance.
§ 63.12	State Authority and Delegations	Yes.	
§ 63.13	Addresses	Yes.	
§ 63.14	Incorporation by Reference	Yes	ASNI/ASME PTC 19.10–1981, Part 10
§ 63.15	Availability of Information/Confidentiality	Yes.	

You may use the mass fraction values in the following table for solvent blends for which you do not have test data or manufacturer's formulation data.

TABLE 4 TO SUBPART OOOO OF PART 63.—DEFAULT ORGANIC HAP MASS FRACTION FOR SOLVENTS AND SOLVENT BLENDS

Solvent/solvent blend	CAS. No.	Average organic HAP mass fraction	Typical organic HAP, percent by mass
1. Toluene	108–88–3	1.0	Toluene.
2. Xylene(s)	1330–20–7	1.0	Xylenes, ethylbenzene.
3. Hexane	110–54–3	0.5	n-hexane.
4. n-Hexane	110–54–3	1.0	n-hexane.
5. Ethylbenzene	100–41–4	1.0	Ethylbenzene.
6. Aliphatic 140		0	None.
7. Aromatic 100		0.02	1% xylene, 1% cumene.
8. Aromatic 150		0.09	Naphthalene.
9. Aromatic naphta	64742–95–6	0.02	1% xylene, 1% cumene.
10. Aromatic solvent	64742–94–5	0.1	Naphthalene.
11. Exempt mineral spirits	8032–32–4	0	None.
12. Ligroines (VM & P)	8032–32–4	0	None.
13. Lactol spirits	64742–89–6	0.15	Toluene.

TABLE 4 TO SUBPART OOOO OF PART 63.—DEFAULT ORGANIC HAP MASS FRACTION FOR SOLVENTS AND SOLVENT BLENDS—Continued

Solvent/solvent blend	CAS. No.	Average organic HAP mass fraction	Typical organic HAP, percent by mass
14. Low aromatic white spirit	64742–82–1	0	None.
15. Mineral spirits	64742–88–7	0.01	Xylenes.
16. Hydrotreated naphtha	64742–48–9	0	None.
17. Hydrotreated light distillate	64742–47–8	0.001	Toluene.
18. Stoddard solvent	8052–41–3	0.01	Xylenes.
19. Super high-flash naphtha	64742–95–6	0.05	Xylenes.
20. Varsol® solvent	8052–49–3	0.01	0.5% xylenes, 0.5% ethylbenzene.
21. VM & P naphtha	64742–89–8	0.06	3% toluene, 3% xylene.
22. Petroleum distillate mixture	68477–31–6	0.08	4% naphthalene, 4% biphenyl.

You may use the mass fraction values in the following table for solvent blends for which you do not have test data or manufacturer's formulation data:

TABLE 5 TO SUBPART OOOO OF PART 63.—DEFAULT ORGANIC HAP MASS FRACTION FOR PETROLEUM SOLVENT GROUPS [a]

Solvent type	Average organic HAP mass fraction	Typical organic HAP, percent by mass
Aliphatic [b]	0.03	1% Xylene, 1% Toluene, and 1% Ethylbenzene.
Aromatic [c]	0.06	4% Xylene, 1% Toluene, and 1% Ethylbenzene.

[a] Use this table only if the solvent blend does not match any of the solvent blends in Table 4 to this subpart and you only know whether the blend is aliphatic or aromatic.

[b] Mineral Spirits 135, Mineral Spirits 150 EC, Naphtha, Mixed Hydrocarbon, Aliphatic Hydrocarbon, Aliphatic Naphtha, Naphthol Spirits, Petroleum Spirits, Petroleum Oil, Petroleum Naphtha, Solvent Naphtha, Solvent Blend.

[c] Medium-flash Naphtha, High-flash Naphtha, Aromatic Naphtha, Light Aromatic Naphtha, Light Aromatic Hydrocarbons, Aromatic Hydrocarbons, Light Aromatic Solvent.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 356

Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 356

[Docket No. 81N–033P]

RIN 0910–AA01

Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) drug products for the reduction or prevention of dental plaque and gingivitis are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Dental Plaque Subcommittee of the Nonprescription Drugs Advisory Committee (NDAC) and is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments by August 27, 2003. Submit reply comments by October 27, 2003.

ADDRESSES: Submit written and reply comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Robert L. Sherman, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: In accordance with part 330 (21 CFR part 330), FDA received on December 3, 1998, a report on OTC antigingivitis/antiplaque drug products from the Dental Plaque Subcommittee (the Subcommittee). FDA regulations (§ 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed rule containing: (1) The monograph recommended by the Subcommittee, which establishes conditions under which OTC antigingivitis/antiplaque drug products are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Subcommittee determined that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Subcommittee determined that the available data are insufficient to classify these conditions under either (1) or (2) of this paragraph; and (4) the conclusions and recommendations of the Subcommittee.

The unaltered conclusions and recommendations of the Subcommittee are issued to stimulate discussion, evaluation, and comment on the full sweep of the Subcommittee's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Subcommittee's findings appear in this document to obtain public comment before the agency reaches any decision on the Subcommittee's recommendations. This document represents the best scientific judgment of the Subcommittee, but does not necessarily reflect the agency's position on any particular matter contained in it.

The Subcommittee was asked for its general recommendations on combination products in which antigingivitis/antiplaque ingredients are combined with other oral health care ingredients. The Subcommittee recommended the following as rational oral health care combination products: (1) An antigingivitis/antiplaque active ingredient combined with an anticaries active ingredient, (2) an antigingivitis/antiplaque active ingredient combined with a tooth desensitizer active ingredient, and (3) an antigingivitis/antiplaque active ingredient combined with an anticaries active ingredient and a tooth desensitizer active ingredient.

However, the agency is not aware of any marketing history of such combination products eligible for the OTC drug review, nor were such combinations submitted to the Subcommittee. Therefore, the agency is dissenting from these recommendations at this time. Data are needed to establish the safety and effectiveness of these combination products. Accordingly, none of the combination products described above may be marketed OTC at this time under this advance notice of proposed rulemaking. The agency invites supporting data and information demonstrating that these combination products can be generally recognized as safe and effective for OTC use.

Based on proposals from industry, the Subcommittee also made general recommendations on testing requirements for final product formulations to be considered effective. The agency is seeking specific information from interested parties on testing protocols, effectiveness criteria, and statistical methods employed to analyze the data from these tests.

The agency notes that the Subcommittee concluded that an active ingredient could be either an antigingivitis agent or an antigingivitis/antiplaque agent. While an ingredient may also be effective in reducing plaque, the Subcommittee stated that the therapeutic endpoint for both antigingivitis and antigingivitis/antiplaque active ingredients is a significant reduction in gingivitis, which can be measured using gingival index scores (see section II.C of this document).

The Subcommittee concluded that there is an association between plaque and gingivitis. The Subcommittee agreed, however, that the exact relationship between plaque and gingivitis cannot be quantified. Because the data submitted to support the effectiveness of stannous fluoride in reducing plaque were inconclusive, the Subcommittee proposed an ''antigingivitis'' statement of identity for this ingredient. However, the Subcommittee's proposed indication for this ingredient includes a reference to plaque reduction.

Although it did not require that antigingivitis ingredients also be effective in reducing plaque, the Subcommittee agreed that ingredients that work primarily by means other than plaque reduction would be inappropriate for use in OTC antigingivitis drug products because these products may mask the symptoms of a more serious condition and cause consumers to delay seeking the advice of a dentist. Because the Subcommittee believed that none of the submitted active ingredients acted other than by reducing plaque, this issue was not further discussed.

Therefore, the agency is seeking comment on the basis for allowing an antigingivitis active ingredient that has not demonstrated effectiveness in reducing plaque to bear labeling statements relating to plaque reduction. More importantly, because of the safety concern that antigingivitis ingredients that work by a mechanism other than plaque reduction (e.g., anti-inflammatory) may give consumers a false sense of security by masking symptoms of a more serious disease, the agency is also seeking comment on whether products that are solely antigingivitis agents, i.e., products that do not significantly reduce plaque,

constitute appropriate OTC drug products.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph (TFM) for OTC drug products for the reduction or prevention of dental plaque and gingivitis. Under the OTC drug review procedures, the agency's position and proposal are first stated in the TFM, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

In accordance with § 330.10(a)(2), the Subcommittee and FDA have held as confidential all information concerning OTC drug products for the reduction or prevention of dental plaque and gingivitis submitted for consideration by the Subcommittee. All submitted information will be put on public display in the Dockets Management Branch (*see* **ADDRESSES**) after June 30, 2003, except to the extent that persons submitting it demonstrate that it falls within the confidentially provisions of 18 U.S.C. 1905, 5 U.S.C. 552(b), or section 301(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to Robert L. Sherman, Center for Drug Evaluation and Research (*see* **FOR FURTHER INFORMATION CONTACT**).

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA). Further, any OTC drug products subject to this monograph that are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an NDA or ANDA. Manufacturers are urged to comply voluntarily with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC drug products bearing antiplaque and antiplaque-related claims was issued in the **Federal Register** of September 19, 1990 (55 FR 38560). These claims included the reduction or prevention of plaque, tartar, calculus, film, sticky deposits, bacterial buildup, gingivitis, diseased, inflamed, or swollen gums, pyorrhea, Vincent's disease, periodontal disease, and tooth-destroying acids.

The Commissioner of Food and Drugs appointed the following members of the Dental Products Panel (the Panel) to review the information submitted and to prepare a report under § 330.10(a)(1) and (a)(5) on the safety, effectiveness, and labeling of those products:

Paul B. Robertson, Chairperson
Charles N. Bertolami (resigned March 24, 1997)
William H. Bowen (term ended October 31, 1995)
Carlos E. del Rio (resigned December 14, 1994)
Julianne Glowacki (term ended October 31, 1994)
Deborah Greenspan
Richard D. Norman
Burton Rosan
Christine D. Wu

The Subcommittee, comprised of two members from the Panel plus five nonvoting consultants to the Panel, was subsequently formed to evaluate the submitted data and report its findings on the safety and effectiveness of ingredients for the reduction or prevention of dental plaque and gingivitis. Each of the following was a voting member of the Subcommittee:

William H. Bowen, Chairperson (term ended April 1995)
Robert J. Genco, Chairperson (from April 1995 to December 3, 1998)
Ralph D'Agostino
Max A. Listgarten
Shelia M. McGuire
Eugene D. Savitt
Stanley R. Saxe
Jorgen Slots (resigned April 12, 1995)
Christine D. Wu

Several nonvoting liaison representatives served on the Subcommittee. P. Jean Frazier, served as the consumer liaison until June 6, 1996, followed by Susan Cohen, until May 1997, and Donald S. Altman, on May 27, 1998. Frederick A. Curro, served as industry liaison (drug) until October 31, 1995, followed by Lewis P. Cancro. Gerald N. McEwen, Jr., served as industry liaison (cosmetic) until October 31, 1996.

On August 27, 1997, oversight of the Subcommittee was transferred from the Panel in the Center for Devices and Radiologic Health (CDRH) to the Nonprescription Drugs Advisory Committee in the Center for Drug Evaluation and Research (CDER).

The following FDA employees assisted the Subcommittee:

Carolyn Tollendi served as CDRH Executive Secretary to the Panel until June 7, 1996. Kennerly K. Chapman served as CDER Executive Secretary to the Subcommittee until December 17, 1996, followed by Andrea Neal until May 9, 1997, followed by Rhonda Stover (interim) until May 1998, followed by Kathleen Reedy. Jeanne L. Rippere served as CDER liaison to the Subcommittee until June 7, 1996, followed by Robert L. Sherman. Stephanie A. Mason served as special assistant to the Subcommittee until June 7, 1996.

The Panel and the Subcommittee were first convened on August 2 and 3, 1993, for a joint organizational meeting. Working meetings of the Subcommittee were held on December 16 and 17, 1993; June 28 and 29, October 11, and December 5, 6, and 7, 1994; April 10, 11, and 12, August 14 and 15, and December 4 and 5, 1995; June 6 and 7, and December 16 and 17, 1996; October 29 and 30, 1997; May 27, 28, and 29, October 22, and December 2 and 3, 1998. Joint meetings of the Panel and the Subcommittee were held on August 2 and 3, 1993, and December 6, 1994. Minutes of most Subcommittee meetings are on public display in the Dockets Management Branch (see **ADDRESSES**).

The following individuals appeared before the Panel and/or the Subcommittee at their own or at the Panel's or Subcommittee's request to discuss drug products for the reduction or prevention of plaque and gingivitis: Gariela Adam-Rodwell, Sam Amer, Daniel M. Bagley, John E. Bailey, Michael L. Barnett, Robert D. Bartizek, Kenneth Baumgartner, William J. Blot, Nancy L. Buc, Gregory A. Burkhart, Lewis P. Cancro, James R. Cheever, Philip Cole, W. Greg Collier, Mark M. Crisanti, Catherine C. Davis, Phillip Derfler, John M. DeSesso, Harvey L. Dickstein, Jerry A. Douglass, Matthew J. Doyle, W. Gary Flamm, William E. Gilbertson, Brian F. Gillespie, David M. Graham, Robert Heller, Jane E. Henney,

Ira D. Hill, Peter B. Hutt, Frederick N. Hyman, Eugene Kamper, Linda M. Katz, Bruce Kohut, Surinder Kumar, Anthony C. Lanzaiaco, Mark S. Leusch, Debbie L. Lumpkins, Milton V. Marshall, Stephanie A. Mason, Stephen F. McClanahan, Stephen H. McNamara, Jerome A. Merski, David Morrisson, Kevin P. Mulry, Anne J. Mustafa, Paul J. Okarma, C. Lee Peeler, Julie H. Rhee, David I. Richardson, Jeanne L. Rippere, Norman A. See, James M. Serafino, Samuel Shapiro, Robert L. Sherman, Chakwan Siew, Gregory Singleton, James Skiles, Thomas J. Slaga, R. William Soller, Steven D. Stellman, George K. Stookey, Howard Strassler, Stanley Tarka, Jr., John M. Treacy, Jack Vincent, Frank A. Volpe, Michael Weintraub, Clifford W. Whall, Jr., Donald J. White, Robert White, Charles Wiggins, David Williams, Gary M. Williams, Deborah Winn, Roy Witkin, and Patrice Wright. No person who so requested was denied an opportunity to appear before the Panel or Subcommittee.

The Subcommittee has thoroughly reviewed the literature and data submissions, listened to additional testimony from interested persons, and considered all pertinent data and information submitted through December 3, 1998, in arriving at its conclusions and recommendations. The Subcommittee wishes to thank the American Dental Association's (ADA) Council on Scientific Affairs for its assistance in providing data, information, and testimony during the course of the Subcommittee's deliberations. The ADA also provided its ''Guidelines for Acceptance of Chemotherapeutic Products for the Control of Supragingival Plaque and Gingivitis'' to the Subcommittee for consideration in making its recommendations on the requirements for safe and effective OTC antigingivitis/antiplaque ingredients.

In accordance with the OTC drug review regulations in § 330.10, the Subcommittee reviewed OTC drug products for the reduction or prevention of dental plaque and gingivitis with respect to the following three categories:

Category I—Conditions under which OTC drugs for the reduction or prevention of dental plaque and gingivitis are generally recognized as safe and effective and are not misbranded.

Category II—Conditions under which OTC drugs for the reduction or prevention of dental plaque and gingivitis are not generally recognized as safe and effective or are misbranded.

Category III—Conditions for which the available data are insufficient to permit final classification at this time.

I. Submission of Data and Information

Under the notices published in the **Federal Register** of September 19, 1990 (55 FR 38650), and March 8, 1991 (56 FR 9915), the following firms made submissions regarding OTC drug products that the Panel/Subcommittee determined contained active ingredients or labeling associated with claims relating to the reduction or prevention of dental plaque and gingivitis.

A. Submissions by Firms

TABLE 1.—FIRMS AND SUBMITTED PRODUCTS

Firm	Submitted Products
American Xyrofin (Morgan, Lewis & Bockius) Washington, DC 20036	Xylitol All Natural Toothpaste, Xytol 32 Dental Cream.
Amer Co., Montecito, CA 93150	Insadol Toothpaste, Pyoralene Toothpaste.
Angus Chemical Co., Northbrook, IL 60062	Hexetidine solution.
Chesebrough Pond's USA Co., Greenwich, CT 06836	CloseUp Antiplaque Toothpaste, Mentadent P Toothpaste.
Church & Dwight Co., Inc., Princeton, NJ 08543	Arm & Hammer Dental Tooth Powder, Dentifrice, and Gel.
CIBA-GEIGY Corp., Greensboro, NC 27419	Irgasan DP, Irgacare MP.
Clinical Product Research, Inc., Shreveport, LA 71109	Prozyme Toothpaste, Anti-Plaquer Oral Rinse, Anti-Plaquer Toothpaste.
Colgate-Palmolive Co., Piscataway, NJ 08855	Colgate Tartar Control Toothpaste, Gelkam Oral Care Rinse, Dentaguard Toothpaste.
E. Merck, Frankfurter, Germany	Thera-Med, Cholordont M.
E. B. Michaels Research Associates, Inc., Milford, CT 06460	Therasol Brush & Rinse Antiplaque Oral Hygiene Solution, Therasol Brush & Rinse Liquid Dentifrice Oral Irrigant.
Leaf, Inc., (Hyman, Phelps & McNamara) Washington DC 20005	Xylitol.
Lion Corp. (America), Memphis, TN 38138	Check-Up Gingival Toothpaste.
Madaus Medtech, Inc., (ACC Consulting Group, Inc.) Washington DC 20036	Parodontax Toothpaste.
Pfizer Inc, New York, NY 10017	Plax Pre-Brushing Dental Rinse.
Pierre Fabre, S.A., 81106 Castres Cedex, France	Eligydium Toothpaste, Eludil Mouthwash.
Prevention Laboratories (formerly 7-L Corp.), Harrisburg, IL 62947	Prevention Mouth Rinse.
Procter & Gamble Co., Cincinnati, OH 45242	Crest Gum Care Toothpaste.

TABLE 1.—FIRMS AND SUBMITTED PRODUCTS—Continued

Firm	Submitted Products
SmithKline Beecham Consumer Brands (Marion Merrell Dow, Inc.), Parsippany, NJ 07054	Cepacol Gold and Mint Mouthwashes, Gly-oxide Liquid.
Vipont Pharmaceuticals, Fort Collins, CO 80522	Viadent Toothpaste and Oral Rinses.
Warner-Lambert Co., Morris Plains, NJ 07950	Listerine Antiseptic Mouthwash.
WhiteHill Oral Technologies, Inc., Hazlet, NJ 07730	Omni-Med Brush-On Tooth Medication, Perio-Med Spray, Take-5 Plaque Fighter Brushless Dentifrice, Smokers Take-5 Plaque and Stain Fighter.
Witkins, Roy T., Westport, CT 06880	Perimed Oral Hygiene Rinse.

In categorizing ingredients as ''active'' and ''inactive,'' the advisory review panels relied upon their expertise and understanding of these terms. FDA has defined ''active ingredient'' in its current good manufacturing practice regulations in § 210.3(b)(7) (21 CFR 210.3(b)(7)) as:

[Any] component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

An ''inactive ingredient'' is defined in § 210.3(b)(8) as ''any component other than an active ingredient.''

B. Active Ingredients Submitted For Review

Labeled Ingredients Contained in Marketed Products Submitted to the Subcommittee:

Alkyl dimethyl amine oxide
Alkyl dimethyl glycine
Aloe vera
Bromchlorophene
Carbamide peroxide
Cetylpyridinium chloride
Chlorhexidine digluconate
Dicalcium phosphate dihydrate
Eucalyptol
Hexetidine
Hydrogen peroxide
Menthol
Methyl salicylate
Peppermint oil
Polydimethylsiloxane
Poloxamer
Povidone iodine
Sage oil
Sanguinaria extract
Sodium bicarbonate
Sodium citrate
Sodium lauryl sulfate
Soluble pyrophosphate
Stannous fluoride
Stannous pyrophosphate
Thymol
Triclosan
Unsaponifiable fraction of corn oil
Xylitol
Zinc chloride
Zinc citrate

Some of these ingredients (bromchlorophene, chlorhexidine digluconate, hexetidine, soluble pyrophosphate, triclosan, unsaponifiable fraction of corn oil) were not marketed for a material time and to a material extent for antigingivitis/antiplaque use in the United States. (See 21 U.S.C. 321(p)(2).) Although the Subcommittee reviewed data to support the safety and effectiveness of these ingredients, they are not eligible for inclusion in the OTC drug review as part of this advance notice of proposed rulemaking and, therefore, are not discussed in this document. In addition, although xylitol was reviewed by the Subcommittee, the two firms that submitted data subsequently withdrew xylitol from consideration by the Subcommittee. Therefore, xylitol is not discussed.

The nomenclature used by the Subcommittee for the ingredients reviewed in this document was the currently accepted terminology stated in the 1996 edition of ''USAN and the USP Dictionary of Drug Names.'' Names recommended by FDA were used for any ingredients which did not have USAN names.

C. Referenced OTC Volumes

All ''OTC Volumes'' cited throughout this document refer to submissions made by interested persons under the call-for-data notices published in the **Federal Register** of September 19, 1990, and March 8, 1991. The information included in these volumes, except for those deletions made in accordance with the confidentiality provisions in § 330.10(a)(2), will be put on public display after June 30, 2003, in the Dockets Management Branch (see **ADDRESSES**).

II. General Statements and Recommendations

A. Definitions

The Subcommittee adopted the following definitions as its intended meaning of terms specifically used in this document concerning OTC drug products for the reduction or prevention of dental plaque and gingivitis. The Subcommittee was aware that some degree of variation with other definitions of the same term may exist.

• *Calculus*. The hard concretions (*i.e.,* calcified plaque) that form on teeth, prostheses, and other hard surfaces. Calculus on teeth is clinically classified into supragingival calculus, which is located on surfaces not covered by the oral mucosa, and subgingival calculus, which is located apical (at the top) to the soft tissue margin of the gingiva.

• *Dental Plaque*. Organized coherent gel-like or mucoid masses consisting of microorganisms in an organic matrix derived from saliva and extracellular bacterial products such as glucans, fructans, enzymes, toxins, and acids. Plaque also contains other cells (e.g., desquamated epithelial cells) and inorganic components such as calcium and phosphate. It adheres to the teeth and other surfaces of the oral cavity. It occurs at the orifice of the gingival crevices and in the periodontal pockets. Plaques may differ markedly in biochemical or microbial composition, and their localization.

• *Gingival Sulcus*. The shallow groove between the tooth and the marginal gingiva.

• *Gingivitis*. An inflammatory lesion of the gingiva that is most frequently caused by dental plaque. Gingivitis is characterized by tissue swelling and redness, loss of stippling (a normal state in which the surface of healthy gingiva is comprised of small lobes), glossy surface, and increased tissue

temperature. The gingiva also may bleed upon gentle provocation such as toothbrushing or may bleed spontaneously. Gingivitis is usually not painful.

• *Oral Hygiene*. Self-administered processes aimed at controlling microbial and other deposits in the oral cavity.

• *Pellicle*. A thin, colorless, translucent film derived from bacterial products and saliva, which forms rapidly on tooth surfaces after natural cleansing or prophylaxis. A few hours after deposition, oral bacteria begin to adhere to the pellicle. These processes represent the earliest stages of plaque formation.

• *Periodontitis*. A disease condition of the periodontium characterized by inflammation of the gingiva, increasing probing depth, and destruction of the periodontal ligament and the adjacent supporting alveolar bone.

• *Tartar*. A synonymous term for calculus.

B. Background and General Discussion of Terms

1. Background

The Subcommittee was charged with the evaluation of the safety and effectiveness of ingredients or combinations of ingredients for the reduction or prevention of plaque and gingivitis as claimed in the labeling of OTC drug products in light of present-day knowledge and standards used in pharmacology, pharmacodynamics, therapeutics, and toxicology.

In making its evaluation, the Subcommittee relied upon factual data found in standard textbooks and scientific articles published by independent investigators in medical, dental, and other scientific journals. Manufacturers included some of these scientific articles in their submissions to FDA to provide a scientific basis for claims made for the safety and effectiveness of their ingredients. Data supplied by manufacturers in unpublished reports of studies performed by private laboratories under contract to the manufacturer or in manufacturers' laboratories were also used by the Subcommittee in making judgments. The Subcommittee also gave due consideration to data from marketing experience and widespread clinical usage when in agreement with basic data from controlled studies and scientific facts.

2. Plaque

Plaque, also known as dental plaque and/or microbial plaque, has been examined for several decades with most of the information explained in the past 25 years. Plaque has a critical etiological role in the development of dental caries, gingivitis, and periodontal disease. It is now clear that dental plaque is a variable biologic community made up of bacteria and a bacterially synthesized matrix. While dental plaque may be combined with other materials such as food particles and sloughed epithelial cells, the combination of these components is called materia alba and is no longer considered plaque.

The precise genera and species of microorganisms in each dental plaque may differ from individual to individual, site to site in the same individual, and within a specific site over time. Plaque from sites of similar clinical health within individual subjects tends to be more similar in composition than plaque from sites in different subjects. Even though there is considerable variation within dental plaques, the composition of plaque is influenced by several factors. The composition of dental plaques is currently known to be affected by plaque age, dietary intake of sucrose and other foods, and other factors (*e.g.,* friction of mastication, oral health, and salivary flow).

Plaque composition is also affected by its location above or below the gingiva. Dental plaques are subdivided into supragingival plaque and subgingival plaque. The distinction resides in the location of dental plaque as either coronal (toward the crown) or apical (toward the root tip) to the soft tissue margin. The microbial populations may differ in plaque from the two locations.

The extracellular matrix synthesized by the bacteria is a significant component of plaque. Because the matrix provides plaque organisms with strong adhesive and cohesive properties, plaque is not easily removed. The tenacity of plaque to adhere to the surfaces of oral structures can be used to distinguish plaque from debris, in that plaque is not removed by flushing the mouth with water.

Plaques differ not only quantitatively but qualitatively in their bacterial composition. For example, microorganisms found in dental plaque include *Actinomyces* species, *Streptococcus sanguis*, *S. mutans*, and other *Streptococcus* species, *Spirochetes*, *Porphyromonas gingivalis*, *Bacteroides forsythus*, and other *Bacteroides* species, *Campylobacter recta*, *Peptostreptococcus micros*, *Eikenella corrodens*, *Actinobacillus actinomycetemcomitans*, *Eubacterium* species, *Fusobacterium* species, *Capnocytophaga* species, and *Prevotella* species. This difference in bacterial composition has a major effect on its pathogenic potential both for periodontal diseases and caries. Some dental plaques are not pathogenic or associated with disease, whereas others are etiologic factors for caries and periodontal diseases. However, the two types of plaque cannot be distinguished visually. The pathogenic potential is dependent upon the microbial composition, including the metabolic products of microbes, dietary patterns, and the intrinsic resistance of the host. It may be prudent to treat all plaques as having pathogenic potential.

3. Calculus

Calculus is a hard concretion that forms on the teeth or dental prostheses through deposition of mineral salts in dental plaques. Human calculus is essentially mineralized dental plaque, which is almost always covered on its external surface by vital, tightly adherent, nonmineralized soft plaque. There may also be loosely held materials associated with calculus such as materia alba, shed bacteria, desquamated epithelial cells, and blood cells. In germ-free animals, calcified deposits may occur in the absence of bacterial accumulation (Ref. 1). However, in humans, virtually all calculus seen clinically likely results from the deposition of calcium and phosphates within bacterial plaques. Calculus formation occurs in an orderly fashion, beginning after 1 or 2 weeks of plaque formation and resulting in full calcification of plaque after 2 to 4 weeks. The process occurs more rapidly in some persons than in others.

Calculus may form subgingivally and is often stained and tenaciously attached to the crown and/or root of the tooth. Calculus may also form supragingivally, coronal (toward the crown) to the gingival margin. Supragingival calculus is found in greater amounts on tooth surfaces adjacent to the openings of the ducts of the major salivary glands. Both subgingival and supragingival calculus are often stained; supragingival calculus can be unsightly, particularly when formed in abundance on labial (facing the lips) surfaces. Although subgingival calculus is a contributing factor in the development of gingivitis, and can also be associated with the progression of gingivitis, periodontitis, and periodontal abscesses, the exact nature of the role of supragingival calculus in gingivitis is not clear. Supragingival calculus can accumulate plaque and act as a nidus (nest) for plaque formation, which can lead to gingivitis.

Calculus facilitates the retention of dental plaque in close proximity to the periodontal tissues. It reduces the

effectiveness of overall hygiene methods to control dental plaque accumulation. Subgingival calculus interferes with the regeneration of lost periodontal attachment.

The removal of calculus is considered a basic step in the prevention and treatment of inflammatory periodontal diseases. The formation of supragingival calculus can be limited through mechanical or chemical methods. Preventing subgingival calculus formation, if possible, would not necessarily reduce gingivitis, because a surface currently free of calculus can still harbor plaque. Present methods do not allow for the predictable prevention of subgingival calculus.

4. Gingivitis

Gingivitis, an inflammation of the gingiva, affects most of the population at one time or another. The signs of gingivitis are tissue swelling and redness, loss of stippling, glossy surface, and increased tissue temperature. The gingiva may also bleed upon gentle provocation, such as toothbrushing, or may bleed spontaneously. Some signs of gingivitis, such as bleeding, can be identified by lay persons.

Gingivitis is a response to injury, often resulting in localization of tissue damage and neutralization of the effects of injurious agents. If the injurious agents cannot be adequately neutralized or eliminated, they may lead to chronic inflammation of the soft tissue and periodontitis. While most cases of periodontitis are believed to start with gingivitis, most cases of gingivitis do not progress to periodontitis. Histologically, gingivitis is characterized by inflammatory exudate or infiltrate, loss of collagen of the gingival connective tissue, and proliferation of the epithelium into the infiltrated tissue. Sometimes the epithelium lining the sulcus (crevice bounded by the tooth and free gingiva) may develop microulcerations. In gingivitis, the junctional epithelium usually is at or near the cementoenamel junction (junction of the tooth crown and root).

Gingivitis, especially when severe, may be self-diagnosable because people can recognize some of the signs of gingivitis, such as bleeding, gingival discoloration, and swelling, which gives rise to pseudopockets (pocket-like structure caused by inflammation of the gingiva without effecting the sulcus base). In the early stages of gingivitis when there is little or no pseudopocket formation, only noncalcified plaque, and little or no calculus, thorough daily oral hygiene may resolve the disease. Under these conditions, self-treatment of gingivitis is appropriate. When OTC drug products for the prevention and control of plaque-associated gingivitis are used as part of a program of good oral hygiene, including regular dental checkups, they can help consumers maintain their gingival health.

The most common form of gingivitis is termed marginal gingivitis and occurs in all individuals at some time. It is limited to the gingivae around the collar of the tooth. However, people are seldom easily able to detect sites with mild gingivitis because there may be no pain or bleeding. Plaque-associated gingivitis, an inflammation of the interdental and marginal gingiva, can be controlled or prevented by removal or inhibition of microbial plaque accumulation. Chemotherapeutic agents can enhance the benefits of traditional methods of oral cleansing by toothbrushing with a dentifrice and regular use of dental floss and other cleaning aids.

Readily available OTC drug products for the prevention and control of plaque-associated gingivitis are intended to play a significant public health role. However, the effects of these products in periodontitis have not been determined in large scale studies. OTC drug products are useful adjuncts to, but do not replace, regular professional care.

In the later stages of gingivitis with the formation of pseudopockets and calculus, it becomes more difficult for people to resolve the gingivitis. Therefore, self-treatment has limited potential for resolution of severe gingivitis, which should be treated as part of a regular professional care program. Gingivitis can progressively worsen and lead to the development of pockets that can be difficult for people to clean.

5. The Interrelationship Between Plaque and Gingivitis

Dental plaque can be causally related to gingivitis. A critical plaque mass at the gingival margin for a particular length of time can initiate change. However, the Subcommittee has no knowledge of any studies where the volume, mass, or amount of plaque can be closely equated with the extent of gingival inflammation. There is a general, positive relationship between supragingival plaque levels and levels of gingivitis. For example, with little or no supragingival plaque accumulation, most often there is gingival health, whereas heavy levels of plaque accumulation, especially at the gingival margin, are often associated with gingivitis.

Plaque forms readily on tooth surfaces in individuals with poor oral hygiene. It takes, histologically, about 3 to 4 days with no oral hygiene in periodontally healthy subjects to develop microscopic evidence of gingivitis. This evidence consists of infiltration of the gingival epithelium, especially the junctional epithelium, with inflammatory cells (including neutrophils), infiltration of the gingival connective tissue with lymphocytes, and beginning loss of collagen.

The Subcommittee does not know how long plaque must be present before gingivitis spontaneously appears. When distinguishing between experimentally induced gingivitis and spontaneous gingivitis (developing under conditions of normal oral hygiene) the following are found: (1) Most subjects over a period of 1 to 3 weeks of cessation of oral hygiene developed gingivitis measurable with clinical indices, and (2) subjects must accumulate a certain level of plaque before clinical signs of gingivitis are apparent. In addition, mature plaque with complex flora appears to be correlated with gingivitis. However, mature plaque, comprised of a complex gram-positive and gram-negative flora with motile organisms, is often associated with spontaneous gingivitis.

The Subcommittee accepts that gingivitis is associated with an accumulation of plaque along the gingival margin but is unaware of any evidence that shows that there is a close correlation between the amount of plaque and the induction of gingivitis, as can be assessed using present day methods. It should be noted that the relationship between the quantity of plaque present and the degree of gingivitis is sufficiently complex such that reductions in plaque mass alone are inadequate to conclude that a therapeutic effect on gingivitis could be expected. Therefore, gingivitis reductions must be measured directly.

6. Periodontitis

Most cases of periodontitis are believed to start with gingivitis, although not all cases of gingivitis lead to periodontitis. Periodontitis is characterized clinically by gingivitis of varying severity, loss of periodontal attachment, increased probing depth, and radiographically detectable loss of alveolar and supporting bone. In advanced disease, the teeth may become increasingly mobile. Progression of gingivitis and the relationship of gingivitis to the onset of periodontitis are not well understood. However, one approach to addressing this relationship comes from human studies in which meticulous oral hygiene leading to excellent plaque control and control of gingivitis appears to prevent the onset of

periodontitis (Ref. 2). It is not clear whether this prevention was due to reduction of supragingival plaque associated with gingivitis, or to meticulous oral hygiene, which also prevents colonization of the subgingival area by periodontal pathogens that are responsible for the onset of periodontitis. What is clear, however, is that in most instances meticulous plaque control appears to lead to reduction of gingivitis and suppression of the onset or rate of progression of periodontitis. Despite periodontal treatment, loss of periodontal attachment and loss of bone often persists. Moreover, people treated for periodontitis may suffer from recurrent gingivitis, root sensitivity, and increased susceptibility to root caries. Periodontitis appears to progress in alternating cycles of exacerbation, which are often asymptomatic and localized, followed by periods of remission. Population studies indicate that systemic conditions such as diabetes mellitus and neutrophil disorders, as well as smoking, increase the risk for developing periodontitis (Refs. 3 and 4).

Histologically, the gingiva becomes inflamed, and the sulcus is deepened to form a pocket which is lined with a pathologically altered epithelial lining, the pocket epithelium. The junctional epithelium is displaced apically. The pocket is largely filled with a subgingival microbiota that is in contact with the adjacent denuded root surface or adherent subgingival calculus deposits. The alveolar process (portion of the upper and lower jaws that forms and supports the tooth sockets) shows evidence of destruction in a ''horizontal'' or ''vertical'' pattern with concomitant loss of the connective tissue attachment to the root.

There are several variants of the disease, including adult periodontitis, early-onset periodontitis (which includes localized juvenile), periodontitis associated with systemic diseases, necrotizing ulcerative periodontitis, and refractory and recurrent periodontitis. Of these, adult periodontitis is the most common form of the disease, and it responds most predictably to scaling, root planing, and plaque control.

7. Oral Hygiene

The Subcommittee's definition of oral hygiene in this document represents the self-administered processes aimed at controlling microbial and other deposits in the oral cavity. Regular oral hygiene, by interfering with plaque accumulation and maturation, favors facultative (able to grow or live with or without oxygen) over anaerobic (growing or living in the absence of oxygen) bacteria. In the process, regular oral hygiene promotes clean dentition and fresh breath, and decreases the risk of plaque-mediated inflammatory changes in the oral cavity. Today, mechanical plaque removal with assorted devices is the primary method for maintaining good oral hygiene. Chemical plaque control (*e.g.,* antiseptic or surfactant mouthrinses) is used primarily as an adjunct to mechanical methods and may be particularly useful for the treatment of surfaces that are not readily accessible to mechanical cleansing, for postsurgical plaque control, and for oral care of handicapped persons. Antibiotics may be used as adjuncts to oral hygiene to suppress or eliminate specific segments of the bacterial population not readily accessible to mechanical cleansing.

C. Drug/Cosmetic Status

The current statutory definitions of ''drug'' and ''cosmetic'' require some consideration when applying them to products for the reduction or prevention of plaque and gingivitis. According to the act, a ''drug'' includes any article ''intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,'' or any article ''intended to affect the structure or any function of the body * * * .'' (*See* 21 U.S.C. 321(g).) According to the act, a ''cosmetic'' includes an article or component thereof ''intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance * * *.'' (*See* 21 U.S.C. 321(i).)

Some products may not clearly fall under one definition or the other. Therefore, another consideration in classifying a product is the ''intended use'' of the product, which is largely dependent on the claims made for the product and the accompanying labeling.[1] In attempting to accurately describe a product's benefits, one of the guiding principles should be to avoid misleading the public with ambiguous claims. Unfortunately, in the case of mouthrinse products, it is easy to make claims that suggest a drug-like benefit, while staying within the guidelines for cosmetic products. Much of the controversy regarding the ''drug'' versus ''cosmetic'' issue for these products revolves around the use of the word ''dental plaque'' or its synonyms (plaque, bacterial deposits, etc.).

1. Antiplaque Products

It is the position of the ADA and the American Academy of Periodontology that the control of dental plaque is a therapeutic procedure basic to the prevention and treatment of caries and periodontal diseases, particularly the latter. The well-established association between dental plaque accumulation and gingivitis demands that effective control of gingivitis be accompanied by effective control of dental plaque. ''Nonspecific'' plaque control involves decreasing the entire microbial mass in a nonspecific manner, i.e., without any attempt at differentially removing or suppressing any particular bacterial species, although shifts in bacterial composition may occur. It is the primary therapy for preventing and controlling periodontal infections that may lead to periodontal inflammatory lesions.

''Specific'' plaque control implies the control of specific pathogens, using strategies that will preferentially suppress certain species or categories of microorganisms. This approach generally requires the use of antimicrobial agents, typically antibiotics, with a specific antimicrobial spectrum. Ideally, the microbial composition of the dental plaque should be assessed before and after treatment to insure that the antimicrobial agents used are appropriate and that the therapy has the desired effect.

The nonspecific control of dental plaque needs to be thorough in order to achieve clinically significant therapeutic benefits. While some OTC oral health care products may be able to reduce the rate of plaque formation to a statistically significant degree, the inhibitory effect on plaque is often insufficient to be considered of therapeutic benefit. It is also highly unlikely that the marginal control of bacterial deposits has a significant relationship to most, if not all, of the cosmetic claims. Outcome variables such as taste and ''feel'' are more likely to be affected by flavoring agents and products that reduce surface tension than by minor variations in plaque accumulation.

The claim that a product significantly reduces dental plaque (statistically speaking) may mislead people into thinking that the reduction is therapeutically significant. Thus, people may purchase a product with the mistaken notion that a therapeutic benefit may be derived from its use, instead of seeking effective care for

[1]The legal opinions of this scientific panel in this area may not and do not necessarily reflect FDA's position.

potential signs and symptoms of disease.

Therefore, the Subcommittee proposes that any reference to the control of dental plaque or its equivalents, with or without qualifications, should be interpreted as a drug claim. In addition, the Subcommittee proposes that an OTC drug product making any reference to the reduction or prevention of dental plaque also must demonstrate a clinically significant effect on gingivitis. Thus, antiplaque claims should not stand alone.

2. Tartar Products

The Subcommittee proposes that any reference to supragingival tartar (calculus) be interpreted as a cosmetic claim. The Subcommittee did not make any reference to subgingival tartar.

D. Labeling of Antigingivitis/Antiplaque Drug Products

Having reviewed the submitted labels of antigingivitis/antiplaque drug products, the Subcommittee recommends that labeling include the following:

1. Ingredients

Antigingivitis/antiplaque agents should contain only active ingredients plus such inactive ingredients as may be necessary for formulation. The label should state the name and quantity of each active ingredient in appropriate units as specified later in this document.

For various reasons, including allergic reactions, safety concerns, and personal preference, individuals may wish to avoid using certain inactive ingredients. It is impossible to make a free choice in this regard unless all the components of drug products are listed on the labels. Therefore, the Subcommittee strongly recommends that all inactive ingredients be listed on the label in descending order of quantity. However, the product should not imply or claim that its inactive ingredients have a therapeutic benefit. The Subcommittee recognizes that although full disclosure of flavoring and coloring ingredients is desirable, this may be impractical and confusing because of the large number of ingredients that may be involved. Thus, flavoring and coloring ingredients may be listed in accordance with present regulations for labeling such ingredients in cosmetic products (21 CFR 701.3).

2. Statement of Identity

The labeling must indicate the principal intended action of the active ingredient as well as the indication for use of the product. The Subcommittee recommends that the statement of identity for active ingredients that demonstrate an antigingivitis effect should be ''antigingivitis.'' The recommended statement of identity for active ingredients that also demonstrate an antiplaque effect should be ''antigingivitis/antiplaque.''

3. Indications

The indications for antigingivitis/antiplaque drug products should be simply and clearly stated, inform the user of the general pharmacological action of the product, and provide a reasonable expectation of results to be anticipated from use of the product. The indications should be specific and confined to the conditions for which the product is recommended. The labeling for any product that contains an active ingredient for which no claim is made would be misleading.

a. *For all antigingivitis products*. The Subcommittee's recommended indication for OTC drug products containing antigingivitis active ingredients is: ''helps (select one of the following: 'control,' 'reduce,' or 'prevent') (select one or more of the following: 'gingivitis,' 'gingivitis, an early form of gum disease,' or 'bleeding gums').''

b. *For antigingivitis products containing stannous fluoride*. The Subcommittee's recommended indication for OTC antigingivitis drug products containing stannous fluoride is the statement in paragraph a. above and/or the following: ''helps interfere with harmful effects of plaque associated with gingivitis.''

c. *For all antigingivitis/antiplaque products*. The Subcommittee's recommended indication for OTC drug products containing antigingivitis/antiplaque active ingredients is: ''helps (select one of the following: 'control,' 'reduce,' 'prevent,' or 'remove') plaque that leads to (select one or more of the following: 'gingivitis,' 'gingivitis, an early form of gum disease,' or 'bleeding gums').''

d. *For antigingivitis/antiplaque products containing the fixed combination of eucalyptol, menthol, methyl salycilate, and thymol*. The Subcommittee's recommended indication for OTC drug products containing the fixed combination of eucalyptol, menthol, methyl salycilate, and thymol is the statement in paragraph c. above and/or the following: ''helps (select one of the following: 'control,' 'inhibit,' or 'kill') plaque bacteria that contribute to the development of (select one or more of the following: 'gingivitis,' 'gingivitis, an early form of gum disease,' or 'bleeding gums').''

4. Directions for Use

The directions for use should be clear, direct, and provide sufficient information to permit safe and effective use of the product. The product labeling should include a clear statement of the smallest usually effective dose and, where applicable, maximum doses (or concentration if more appropriate) per time interval. If dosage varies by age, the directions should be broken down by age groups. The Subcommittee used directions from the supportive clinical trials as the basis for its recommended directions for use.

a. *For antigingivitis or antigingivitis/antiplaque dentifrice products*. The directions for use for antigingivitis or antigingivitis/antiplaque dentifrice drug products should be consistent with the directions required in the final monograph for OTC anticaries drug products in 21 CFR 355.50(d)(1).

b. *For antigingivitis/antiplaque oral rinse products*. ''Adults and children 12 years of age and older: Vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse. Children 6 years to under 12 years of age: supervise use. Children under 6 years of age: do not use.''

5. Warnings

Labeling of antigingivitis and antigingivitis/antiplaque products should include warnings against unsafe use, side effects, and adverse reactions.

a. *For all antigingivitis and antigingivitis/antiplaque products*. ''If more than used for brushing (rinsing) is accidentally swallowed, get medical help or contact a Poison Control Center right away. If gingivitis, bleeding, or redness persists for more than 2 weeks, see your dentist. See your dentist immediately if you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.''

b. *For antigingivitis products containing stannous fluoride*. ''Keep out of the reach of children under age 6.''

6. Additional Labeling Statements

For stannous fluoride dentifrice drug products. In addition to warning statements, the following statements should appear on the label of antigingivitis dentifrice drug products containing stannous fluoride: ''This product may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not

harmful or permanent and may be removed by a dentist.''

E. Combination Drug Products

1. General Combination Policy

The Subcommittee recognizes that there may be a reason for combining active ingredients in certain OTC drug products. However, such combinations must be based on a sound and logical scientific rationale. The Subcommittee applied the OTC drug review regulation in § 330.10(a)(4)(iv) in developing a combination policy for antigingivitis/antiplaque drug products. The Subcommittee believes that it is rational to combine oral health care ingredients that meet the regulatory requirements as well as the criteria adopted by the Subcommittee, together with suitable inactive ingredients, provided that: (a) Each active ingredient makes a contribution to the claimed effect, (b) the active ingredients are safe and effective and combining the ingredients does not decrease the effectiveness of any individual ingredient, (c) combining the ingredients does not decrease the safety of the combination compared to a single ingredient, (d) the inactive ingredients are safe and do not interact with or otherwise inhibit the effectiveness of the active ingredients, (e) there is a significant target population that can benefit from the use of the combination, and (f) the combination contains adequate directions for use and is labeled with adequate warnings against unsafe use.

The Subcommittee concludes that the same general principles apply when an active ingredient from a different pharmacological class reviewed by another OTC drug advisory panel is combined with an active ingredient reviewed by this Subcommittee. The rationale for such combinations should be evaluated by FDA according to the combination policy set forth in the reports of both advisory panels and in accordance with the agency's regulations.

2. Criteria for Category I Combination Products

The Subcommittee recommends that each claimed active ingredient in a combination product must make a significant contribution to the claimed effects of the product. Further, two Category I active ingredients from different pharmacological groups may be combined to treat different symptoms concurrently if each Category I active ingredient is present within its established dosage range, the combination is rational, there is a significant target population that suffers from the concurrent symptoms, and the combination is as safe and as effective as each individual active ingredient used alone.

3. Category I Combination Antigingivitis/Antiplague Drug Products

The Subcommittee considers it rational to combine antigingivitis/antiplaque agents with an anticaries agent. It is also rational to combine antigingivitis/antiplaque agents with a tooth desensitizing agent. In addition, the Subcommittee considers it rational to combine an antigingivitis/antiplaque agent with an anticaries agent and a tooth desensitizer in a single drug product. Further, the Subcommittee believes that although it has been presented with no scientific basis to recommend the combination of two or more antigingivitis ingredients, two or more antigingivitis/antiplaque ingredients, or combinations of antigingivitis and antigingivitis/antiplaque ingredients, it is theoretically reasonable to combine such ingredients, provided it is demonstrated that each ingredient contributes to the claimed effect and does not decrease the safety or effectiveness of another active ingredient.

F. Testing of Antigingivitis/Antiplaque Drug Products

The Subcommittee concludes that the single active ingredients and the fixed combination of eucalyptol, menthol, methyl salicylate, and thymol placed in Category I have been shown through clinical trials to be safe and effective for OTC use in the control of gingivitis and plaque. However, because product formulation can have a significant impact on the effectiveness of these active ingredients, the Subcommittee recommends that OTC antigingivitis/antiplaque drug products demonstrate their effectiveness through the testing described below. Based on the varying mechanisms of action of the Category I active ingredients, the Subcommittee recommends testing specific to each of the Category I active ingredients to demonstrate their effectiveness in traditional dosage forms (dentifrice, gel, paste, or rinse).

1. Changes in Traditional Dosage Forms

The Subcommittee recommends that drug products containing Category I active ingredients formulated in dosage forms other than those reviewed by the Subcommittee be required to demonstrate antigingivitis/antiplaque effectiveness by a single 6-month, randomized, controlled, clinical trial.

2. Final Formulation Testing

The following testing should be conducted on the product formulation, a standard formulation with effectiveness documented by clinical trials, and a negative control. In general, for a product to be considered effective it must demonstrate that it is statistically substantially equivalent to the standard formulation and statistically superior to the negative control as assessed by reasonable statistical analyses. For validation of the study, the standard must be statistically superior to the negative control. However, during the rulemaking process, the criteria appropriate for these tests should be provided by the product manufacturers.

a. *Cetylpyridinium Chloride Rinse*.

• Determine the in vitro antimicrobial activity of the product against representative plaque organisms commonly associated with gingivitis. Representative organisms include, but are not limited to, typed stains of: *Actinomyces viscosus*, *F. nucleatum*, *P. gingivalis*, *Prevotella intermedia*, *Bacteroides forsythus*, *Candida* species, *S. mutans*, and gram negative enteric rods. Testing to determine a product's in vitro antimicrobial activity should include minimal inhibitory concentration (MIC) assays, or 30-second kill-time studies, as appropriate.

• Demonstrate the availability of the active ingredient using a Disk Retention Assay (DRA). A suggested method for this assay is included in a submission to the Subcommittee (Ref. 5).

• Demonstrate the biological activity of the formulation using an ex vivo Plaque Glycolysis and Regrowth Model (PGRM). A suggested protocol for this assay is included in a submission to the Subcommittee (Ref. 5).

b. *Stannous Fluoride Dentifrice*.

• An *in vitro* determination of antimicrobial activity against representative plaque organisms commonly associated with gingivitis (described in paragraph F.2.a. of this document) is recommended. Testing to determine a product's in vitro antimicrobial activity should include MIC assays, 30-second kill-time studies, or plaque biofilm assays, as appropriate.

• Demonstrate the biological activity of the formulation using ex vivo PGRM (protocol for assay, Ref. 5).

c. *Fixed Combination of Eucalyptol (0.092 percent), Menthol (0.042 percent), Methyl Salicylate (0.060 percent), and Thymol (0.064 percent) Rinse*.

• Determine the *in vitro* antimicrobial activity using 30-second kill-time studies with both standard laboratory

strains and wild-type organisms obtained from saliva sampling. Representative organisms are listed in paragraph F.2.a of this document. Conduct kill-time testing using an exposure time of 30 seconds in the presence of exogenous protein. Use an initial inoculum of 1-percent transmission.

• Demonstrate the *in vivo* activity of the formulation through a short-term experimental gingivitis study of at least 2 weeks duration. A representative protocol, comparing the test product, a clinically tested standard, and a negative control, is included in a submission to the Subcommittee (Ref. 6). The criterion for study validation is statistically significant differences in plaque and gingivitis scores between the clinically tested standard and the negative control. To establish comparability to the standard mouthrinse in this test (or another generally accepted statistical test of clinical comparability), the new mouthrinse formulation must satisfy the ''at least as good as'' statistical criteria for both plaque and gingivitis scores, i.e., at least statistically significantly comparable or equivalent to the clinically tested standard.

G. Inactive Ingredients

1. Alcohol in Oral Health Care Drug Products

Many OTC mouthrinses contain alcohol (up to 26 percent or more). Concerns were raised when published reports and other information appeared to show a possible risk of developing oropharyngeal cancers from daily use of mouthrinses containing high concentrations of alcohol. After reviewing the available data, the Subcommittee has the following comments concerning high alcohol-content mouthrinses and cancer of the buccal cavity and pharynx (oral).

a. *Oral cancer*. Based on the 1993 statistics for oral cancer in the United States (Ref. 7), the buccal cavity and pharynx are the eighth most common site of cancer, representing approximately 3 percent of all cancers reported. Approximately 30,000 people per year develop oral cancer. The ratio of men to women developing oral cancer is about 2 to 1. The 5-year survival rate for persons with oral cancer is about 33 percent for African-Americans and 50 percent for Caucasians.

Alcohol consumption and tobacco smoking/chewing account for approximately three-fourths of oral cancers in the United States (Refs. 8 through 13). Other less clearly established causal factors include poor dental conditions, oral infections, nutritional deficiencies, and possibly high alcohol-content mouthrinses (Refs. 14 through 19).

b. *Adverse reactions associated with mouthrinses*. A drug that ordinarily causes no adverse effects with short-term exposure may produce pathologic tissue changes after chronic usage. Prolonged usage of a drug and/or its metabolites combined with various compounds in the mouth may result in cumulative effects in oral tissues. Mouthrinses should be evaluated for chronic, long-term usage and resulting manifestations (Ref. 20).

Mucous membranes of the mouth can absorb mouthrinse ingredients, which may pass systemically into the bloodstream. The literature describes local adverse reactions from mouthrinse usage, ranging in severity from irritancy and sensitization to cancer (Refs. 21, 22, and 23).

Some case-control studies suggest a causal association between mouthrinse use and oral cancer risk, most recently in the largest study to date by the National Cancer Institute (Ref. 24). The cancer risk seems to be greater in females (60 percent) than in males (40 percent) and varies in proportion to dose, tending to increase with increasing duration and frequency of use and the alcohol concentration of the mouthrinse (Ref. 24). Other researchers have found no evidence of an increased cancer risk associated with mouthrinses (Refs. 25, 26, and 27).

The reported risk of oral cancer pertains to mouthrinses with alcohol-contents of 25 percent or higher. However, since these mouthrinses also contain other active ingredients, such as essential oils with lipophilic, membranotropic effects, some high alcohol-content mouthrinses may affect tissues by a variety of mechanisms.

Studies that have evaluated the potential for alcohol in mouthrinses to cause cancer have a number of shortcomings: (1) Investigations based on subject accounts without benefit of medical records or other written documentation, (2) unreliable classification of exposure to known risk factors such as alcohol and tobacco in study subjects, (3) lack of consistent dose-response relationships based on frequency and/or duration of mouthrinse use, and (4) combining cases of cancer of the buccal cavity and pharynx despite the fact that mouthrinses are in direct contact only with the mucosa of the buccal cavity.

c. *Alcohol and oral cancer*. Although consumption of alcoholic beverages is a known risk factor for oral cancer, pure alcohol does not show a direct carcinogenic action in laboratory animals or humans. The cancer associated with alcoholic beverages is probably related to contaminating carcinogens. These include urethane produced from urea reacting with ethyl alcohol during yeast fermentation of fruit juices, and n-nitrosamine compounds catalyzed from precursor nitrite and amines, amides, or other nitrosatable agents. Commercial mouthrinses contain distilled ethanol free of these contaminating carcinogens. Other findings suggest an ability of ethanol to enhance the conversion of procarcinogens to mitogens, and of ethanol's metabolite acetaldehyde to produce deoxyribonucleic acid (DNA) abnormalities in human cells.

Animal studies have indicated that ethanol may also function as a cocarcinogen, in association with other substances that are true carcinogens (Ref. 28). Alcohol may act by facilitating the penetration of carcinogens into the mucosa (Refs. 29 through 33). Weak carcinogenic nitrosamines and other compounds have been shown to have enhanced carcinogenicity in the presence of alcohol (Ref. 33). Alcohol may act directly on epithelial cells by altering intracellular metabolism and rendering cells more susceptible to carcinogens (Ref. 28).

Based on these studies, the Subcommittee recommends that further studies on the possible cancer risk associated with high alcohol-content mouthrinses be conducted. These studies should include testing various components of the mouthrinse and pertinent dietary ingredients.

d. *Abuse and misuse of mouthrinses*. Although some OTC mouthrinses contain alcohol, the potential for development of drug tolerance and addiction due to use of these products seems negligible. However, misuse of any mouthrinse product may occur if the product gives the user a false sense of security, diminishing the users's desire to seek professional advice. This problem may be particularly acute for mouthrinses that may subdue signs and symptoms of a gingivitis infection without resolving a more severe, underlying periodontitis infection. A label warning should alert the consumer to this danger.

e. *Alcohol as a facilitator*. While the Subcommittee recognizes that the combination of alcohol and tobacco is associated with a marked increase in the incidence of oral cancer as compared to exposure to tobacco alone, it concludes that the mechanism of this synergism is unknown. Animal studies (Ref. 28) have shown that alcohol has a topical

potentiating effect in the production of squamous cell carcinoma in animal cheek pouches treated with 7,12–dimethylbenz(a)-anthracene (DMBA). Decreased latency and larger tumors were observed as compared to controls.

Other animal studies (Refs. 29, 30, 32, and 33) have demonstrated similar effects. These studies were older and implied a model that is not comparable to what happens in humans. Moreover, some carcinogens are extremely species-specific, and limited information is available on direct experiments performed on the human mucosa.

If the synergistic effect of alcohol in causing an increased risk of oral cancer is attributed to a topical effect, as noted in the animal studies, then daily use of oral rinses containing a high concentration of alcohol may have a tissue altering effect. Whether this may be as significant as alcoholism in the epidemiology of oral cancer warrants continued investigation.

One of the few mechanistic evidences for a local alcohol effect has been demonstrated by permeability studies. In the presence of nicotine, alcohol had a greater relative effect on penetration of carcinogens in and across the floor of the oral mucosa (floor of the mouth, oral mucosa) (Ref. 34). Also, pharmaceutical studies have demonstrated that the oral mucosa can have a reservoir effect, so that compounds are rapidly taken up and held in the oral epithelium, extending the duration of their effect (Ref. 35). This mechanism has recently been utilized in a formulation using alcohol to increase permeability, thereby obtaining systemic delivery of proprietary drugs after only a mucosa exposure.

It is clear that further research is needed to investigate the role of alcohol as an enhancer of the penetration of carcinogens through the oral mucosa. In addition, the threshold of alcohol concentration necessary to achieve this phenomena needs to be investigated.

2. The Subcommittee's Conclusions and Recommendations Regarding Alcohol Content in Mouthrinses

On June 6, 1996, the Subcommittee, along with other scientific experts (e.g., epidemiologists and statisticians) held a workshop (Ref. 36) to further consider whether alcohol-containing mouthrinses contributed to oral cancers. Although some studies have implicated high alcohol-content mouthrinses as a possible cause of oral/pharyngeal cancer, the relationship between high alcohol-content mouthrinses and oral/pharyngeal cancer is not clear. The findings of various studies are contradictory and do not show a consistent dose-response relationship. A major difficulty in deciding cause and effect in these studies is the possibility of confounding by known risk factors, such as high alcoholic beverage consumption and tobacco use.

The Subcommittee reviewed new data consisting of a specificity analysis (Ref. 37) using data from the Winn et al. study (Ref. 24) and a preliminary analysis from an unpublished study of laryngeal, esophageal, and oral cancer (Ref. 38). In addition, the Subcommittee reviewed seven case-control studies, published between 1979 and 1991 (Refs. 12, 13, and 23 through 27), of the association between mouthrinse use and oral cancer. These studies are described below.

Weaver et al. (Ref. 23) reported the use of alcohol-containing mouthrinses among 11 subjects with oropharyngeal cancer who indicated that they did not smoke or drink alcoholic beverages. These cases became part of a case-control study regarding an association between alcohol-containing mouthrinses and oropharyngeal cancer. Although the study was unevaluable, it generated the hypothesis that led to subsequent studies.

A 1983 case-control study by Wynder et al. (Ref. 12) evaluated the relationship between mouthrinses and oropharyngeal cancer. No positive findings were reported for men. In women, the relative risk, unadjusted for smoking and alcoholic beverage consumption, was statistically significant for daily use of mouthrinses. However, there was no consistent relationship for duration or frequency of use. Further, a refined analysis using a multiple logistic model indicated no association between mouthrinse use and oropharyngeal cancer. The investigators concluded that, due to the absence of a dose-response relationship and the possibility of confounding by tobacco and alcoholic beverage use, it was not possible to attribute an association between daily mouthrinse use and oral cancer in women.

A 1983 case-control study by Blot et al. (Ref. 13) included female subjects from a previous study of snuff use. A relative risk of 1.94 was reported for women who used a mouthrinse but did not use tobacco products. However, this was not statistically significant (confidence interval = 0.8 to 4.7), and there were no consistent dose-response relationships for years of use, frequency of use, time retained in the mouth, or concentration (i.e., diluted vs. full strength). Because dose-response relationships are important in considering whether there is an association between mouthrinse use and oral cancer, the Subcommittee concludes that this study does not support a causal association between alcohol-containing mouthrinses and oropharyngeal cancer.

The Subcommittee reviewed three additional case-control studies published between 1985 and 1989 (Refs. 25, 26, and 27). One study by Kabat *et al.* (Ref. 26) is of particular interest because, although mouthrinses were not associated with increased oral cancer risk in terms of frequency or duration of use, cases were significantly more likely than controls to state that mouthrinses were used to disguise breath odors caused by alcoholic beverages or tobacco. In contrast, similar proportions of cases and controls reported using a mouthrinse to conceal food odors or for mouth infections or dental problems. The Subcommittee concludes that these findings indicate that mouthrinse use may be serving as a surrogate for underreported drinking and/or smoking.

A 1991 study by Winn et al. (Ref. 24) was the largest case-control study among the seven published studies evaluating mouthrinses (866 cases and 1,249 controls). Odds-ratios for oropharyngeal cancer risk after adjusting for tobacco and alcoholic beverage use were 1.4 (confidence interval 1.0 to 1.8) in men and 1.6 (confidence interval 1.1 to 2.3) in women. Dose-response relationships, such as duration of use, frequency of use, and age when use started, were questionable, with no trend analysis of these relationships reported. This study also showed a decreased odds-ratio for dental X-rays. There is no biologically plausible reason to expect X-rays to be protective against oral cancer, and the negative association is likely a reflection of less frequent visits for dental care by cases versus controls. However, the negative association could not be eliminated by adjustment for factors that are relevant to quality of dental care (e.g., education).

Thus, this study was capable of producing a statistically significant noncausal association that could not be eliminated by adjustment of the data. Further, regarding the odds ratio for mouthrinse use, confounding due to underreported use of tobacco and alcoholic beverages, both strong risk factors for oropharyngeal cancer, could result in an artificially elevated odds ratio. Such a false association can be produced even though the extent of underreporting is the same in both the case and control groups (Ref. 39). Information in the published literature indicates that especially drinking and sometimes smoking are underreported (Refs. 40 through 44). The

Subcommittee concludes that these studies do not support a causal relationship between the use of alcohol-containing mouthrinses and oropharyngeal cancer.

The Subcommittee reviewed unpublished new data that included a specificity analysis (Ref. 37) of the data from the Winn et al. study (Ref. 24). This analysis excluded 75 cases (38 men and 37 women) who did not have oropharyngeal cancer (*i.e.,* epithelial cell cancer of the mouth) based on evaluation of the International Classification of Diseases codes. The excluded cases consisted primarily of tumors of the minor salivary glands and sarcomas and lymphomas that happened to occur within the oral cavity. Excluding these cases left 535 and 256 cases of oropharyngeal cancer in men and women, respectively. Evaluation of smoking and alcoholic beverage use indicated that both of these risk factors were more strongly associated with the included cases than with the total number of cases (included plus excluded). Neither smoking nor alcoholic beverage use were associated with the excluded cases. This analysis indicated that the excluded cases may not have the same etiology as the included cases and, therefore, should not have been included in the original analysis conducted by Winn et al. (Ref. 24) to evaluate risk associated with mouthrinse use.

When odds ratios for mouthrinse use in women were calculated for the included cases, they were decreased relative to the odds ratios for total cases originally reported by Winn et al. (Ref. 24). This was true for a number of subanalyses, including duration of use, frequency of use, age when use began, and alcohol concentration. Higher odds ratios for mouthrinse use among the excluded cases suggested that mouthrinse use was more strongly associated with excluded cases than with included cases. However, there is no biologically plausible explanation for this finding since the excluded cases represent a variety of tumor types whose origins cannot be presently explained by topical exposure to ethanol via mouthrinse use. In addition, the data were inconsistent with a dose-response with respect to duration of use, frequency of use and age when mouthrinse use started, which suggests that this finding may be related to information bias rather than a causal association. The specificity analysis among male cases was less informative than for females and supports neither a causal hypothesis nor information bias as the explanation for the weak association with mouthrinse use (odds ratio 1.4) originally reported by Winn et al. (Ref. 24). The limited value of the specificity analysis in males is likely related to the fact that: (1) The excluded male cases represented a smaller percentage of the total male cases and (2) the odds ratio for mouthrinse use in males is smaller than it is in females. Both of these factors make it difficult to detect any shifts in odds ratios. The Subcommittee concludes that, overall, the specificity analysis of the Winn et al. study (Ref. 24) indicates that this study does not support a causal association between mouthrinse use and oropharyngeal cancer (Ref. 37).

Preliminary analyses from an unpublished case-control study of laryngeal, esophageal, and oral cancer (Ref. 38) showed that the odds ratio for mouthrinse use in males and females combined (adjusted for cigarette and alcoholic beverage use) was 1.4 (confidence interval 1.0 to 2.0). However, the analyses of frequency, duration, and age when use started showed inconsistencies that question a causal relationship. In addition, when the data were evaluated with respect to alcohol content, the highest odds ratio (unadjusted for smoking and alcoholic beverage use) was found among users of mouthrinses containing no alcohol (e.g., salt water, vinegar, baking soda in water). The Subcommittee concludes that this finding differs from the Winn et al. study (Ref. 24) results showing that odds ratios were elevated only for mouthrinses having the highest alcohol content and is inconsistent with the hypothesis of a causal association between alcohol-containing mouthrinses and oral cancer.

An unpublished review of the literature concerning possible mechanisms of alcoholic beverage consumption and oral cancer risk was submitted to the Subcommittee (Ref. 45). Although alcoholic beverage consumption is a known risk factor for oral cancer and the literature on experimental mechanistic studies (e.g., in vitro and animal studies) raises speculations concerning how the biological effects of alcohol may modulate cancer risk, the Subcommittee concludes that the relevance of these studies to mouthrinse use in humans has not been established.

Based on the studies reviewed, the Subcommittee concludes that the available data do not support a causal relationship between the use of alcohol-containing mouthrinses and oral cancer. The vote was unanimous with the Chairman abstaining. The Subcommittee acknowledges that epidemiologic research on oropharyngeal cancer will continue, and that the conclusion reached by the Subcommittee is based on the data available at the time of its deliberations. However, because some studies did report a relationship between the use of high alcohol-content mouthrinses and pharyngeal cancer, the Subcommittee agrees that further studies should be conducted to determine the relationship between high alcohol-content mouthrinses and oral/pharyngeal cancers. In addition, the Subcommittee recommends that all mouthrinses should be labeled in a readily readable manner with the alcohol concentration in percent, *e.g.,* ''Contains _ % alcohol'' on the principal display panel.

H. General Guidelines on Safety and Effectiveness

1. General Statement

The Subcommittee arrived at its conclusions and recommendations regarding the safety and effectiveness of all active ingredients after considering all pertinent data and information submitted. The Subcommittee adopted the following general ''points to consider.'' These are not intended to restrict investigators, but are recommendations for studies recognized as desirable approaches to determine the safety and effectiveness of OTC antigingivitis/antiplaque active ingredients. In some cases, other methods may be equally applicable, or newer methods may be preferable. Also, these recommended studies may not produce all information necessary to determine that an ingredient is generally recognized as safe and effective.

2. Guidelines

An OTC drug included in a monograph is described in § 330.10 as generally recognized among qualified experts as safe and effective for use and as not misbranded. Proof of the safety of an OTC drug ingredient consists of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use. This proof shall include results of significant human experience during marketing. General recognition of safety shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data. Proof of effectiveness of an OTC drug ingredient consists of controlled clinical investigations as defined in § 314.126(b) (21 CFR 314.126b)) by qualified experts to show that the drug provides clinically significant relief of the type claimed in its labeling. The latter requirement may be waived if it is not reasonably applicable to the drug in question or

essential to the validity of the investigation and an alternative method of investigation is adequate to substantiate effectiveness. Effectiveness may be corroborated by partially controlled or uncontrolled studies, and reports of significant human experience during marketing. General recognition of effectiveness shall ordinarily be based upon published studies that may be corroborated by unpublished studies and other data.

The characteristics of adequate and well-controlled studies have been developed over a period of years and are described in § 314.126. Studies supporting the safety and effectiveness of OTC drug ingredients should provide sufficient details of study design, conduct, and analysis to allow a critical evaluation of the data in relationship to the above characteristics.

In several proposed and final monographs, the agency has stated that, in order for an active ingredient to be included in an OTC drug monograph, it is necessary that the ingredient be adequately characterized and that these standards be published in an official compendium such as the United States Pharmacopeia (USP) or the National Formulary (NF) (58 FR 28194 at 28284). Such specifications are necessary to assure the identity, strength, quality, and purity of the active ingredient. Therefore, the Subcommittee recommends that a full description of the ingredient, including its physical and chemical characteristics and stability, be provided, and that manufacturers contact and work with the USP to develop monographs for ingredients that are not currently included in that compendium. For ingredients that are currently included in an official compendium, reference to the current edition of the USP or the NF may satisfy this requirement.

a. *Safety*. The Subcommittee's determination of the safety of single ingredients and ingredient combinations is based on the following criteria: (1) The incidence and risk of adverse reactions and significant side effects when the ingredient was used according to adequate directions in the labeling, (2) the margin of safety under conditions of normal use and the potential for harm that might result from abuse or misuse under conditions of widespread OTC availability, (3) the potential for inducing untoward effects on the oral tissues, including irritation, ulceration, inflammation, erosion, and minor effects such as discoloration of the teeth, restorations, and prostheses, etc., and (4) assessment of the benefit-to-risk ratio. The Panel further states that microbial safety should be determined through clinical evaluation of changes in representative oral microbial populations (*e.g.,* the possible emergence of opportunistic organisms or potential pathogens), in order to assure that there is no adverse change in the balance of the oral microflora under conditions of expected OTC use.

i. *Toxicological studies*. A variety of toxicological data can be obtained to demonstrate that an active ingredient is safe. The Subcommittee recommends that manufacturers conduct the applicable studies discussed below and emphasizes that these recommendations do not preclude the use of alternative comparable methods that are currently available or better methods that may be developed in the future. The Subcommittee recommends that the following data be available for the active ingredient(s) intended for use on the mucous membranes of the mouth and throat.

Testing the effects of various ingredients on animal subpopulations that can reflect human subpopulations should be considered (e.g., hyposalivation studies in nonsalivating animals). Adequate, acceptable, controlled in vivo studies of acute and chronic toxicity in several species of animals should be available. Such studies may include single-dose gavage studies, repeat-dose gavage studies, oral irritation studies, pharmacokinetic/biodistribution studies, and dermal sensitization studies. Information regarding the genetic, reproductive toxicologic, and carcinogenic potential should be considered for ingredients that are going to be used daily on a long-term basis. It is not necessary to determine the LD_{50} (lethal dose for 50 percent of the test animals) of the ingredient. However, information about the minimal lethal dose would be useful.

All or some of the recommended toxicological studies may not be necessary for all active ingredients. Some circumstances that might preclude an ingredient from the above testing are: (1) It is already generally recognized as safe, (2) it is a direct food additive, (3) it has been used previously in approved dental drug products, or (4) it is the subject of an OTC drug monograph with a different but similar or related use at a similar concentration and for a similar time period. Published articles may be considered in lieu of the testing recommended above.

One of the Subcommittee's primary concerns regarding antigingivitis/antiplaque ingredients is whether or not swallowing the active ingredient presents a threat to the user. The Subcommittee recommends that gavage studies be used to address concerns about potential systemic toxicity unless applicable published or unpublished studies have been conducted using a dietary admixture mode of administration and comparable toxicokinetics can be shown between gavage and dietary modes of administration. Single administration gavage studies are typically performed using a limit-value test in the rat at a specified high dose to evaluate acute toxicity potential (Refs. 46, 47, and 48). In the absence of adequate dietary admixture studies, repeat dose gavage studies may be employed to evaluate systemic toxicity from multiple exposures. The test article is administered to rats on a number of consecutive days.

Where there is a concern that antigingivitis/antiplaque active ingredients may induce untoward effects on the oral mucosa, the dosage to be used for these studies should be justified based on the concentration of human exposure levels. An appropriate dosage range may extend, for example, from a low dose comparable to swallowing a single dose of mouthrinse or the amount remaining following expectoration of a mouthrinse to a high dose that either causes dose-limiting toxicity or is several orders of magnitude greater than the clinical exposure levels. Such studies usually use four applications per day for a period of 28 consecutive days. The oral irritation should include both a negative and a positive control group. All test articles should be applied in an identical manner. A negative control group may consist of animals that are treated with either water or saline, and the positive control is a group of animals that are treated with the solution that is known to cause a minimal degree of irritation without being inhumane to the animals (e.g., 5-percent solution of sodium lauryl sulfate).

The Subcommittee recommends that the study include abraded mucosa in order to determine whether the test ingredient delays or prevents the healing of oral lesions. The parameters to include are any gross observations of changes in the oral tissue, such as sloughing, ulceration, or bleeding. Following the sacrifice of each animal, the histopathology of oral tissues should be examined.

ii. *Studies in older adults*. The Subcommittee is concerned that older adults might be at greater risk for potential systemic toxicity from the use of antigingivitis/antiplaque active ingredients. This is of particular concern because of the continually

increasing size of the older adult population, who are retaining more natural teeth and becoming a significant population for use of antiplaque/antigingivitis products.

Publications have described differences in drug responses in the elderly. Changes in pharmacokinetics have been reviewed (Ref. 49). Absorption can theoretically be altered by noted changes in gastrointestinal function, but the majority of studies have shown no difference in rate or extent of absorption of the drug examined. Distribution of a drug within the body is affected because fat content of body weight increases and intracellular water decreases. For example, albumin concentration is reduced and drugs which bind to albumin are more free to distribute to the rest of the body. Hepatic metabolism may be altered. Reduction of blood flow to the liver will decrease clearance of some drugs. Renal excretion is affected in some older adults by loss of renal mass and functional nephrons.

Russell (Ref. 50) noted that despite numerous reports in the literature of impaired GI function with aging, most functions remain relatively intact because of the large reserve capacity of the intestine, pancreas, and liver. In a review critically analyzing available information on age-related changes in the digestive and absorptive GI physiology of lipids, data suggested lipid digestion and absorption are well-preserved in the aging. However, intercurrent illness or experimental stress may produce impairment in aging animals and humans that is not seen in younger controls (Ref. 51).

Atillasoy and Holt (Ref. 52) noted that the GI tract represents an organ system characterized by rapid proliferation. Contrary to generally held prejudices, the authors write, a state of hyperproliferation, not hypoproliferation, occurs in the epithelial cells of the stomach, small intestine, and large intestine of stable-fed, aged rodents when compared to young adult rodents.

In a gavage study (Ref. 53) Yamada et al. investigated renal ammoniagenesis in isolated nephron segments from control, acidotic senescent (exhibiting deteriorating teeth due to aging), and young adult rats. No significant difference was seen in glutamine-dependent ammonia production in the segments. However, ammonia production in glomeruli from old rats was significantly greater than in young rats.

There appear to be no available consistent findings to warrant that additional gavage studies of antigingivitis/antiplaque active ingredients in older animals will produce more meaningful findings relative to older adults than the usual gavage studies in adult animals. This is due to the great diversity which exists in the health and fitness status of the elderly population. The Subcommittee considers a comment by Ahronheim (Ref. 54) appropriate:

Although much has been written about age-related alterations in drug disposition, there is disagreement as to the extent and inevitability of these changes. Studies focusing on aged individuals suffer from several problems. Cross-sectional studies comparing young and old subjects sometimes compare young, healthy individuals with aged subjects gathered from hospitals or nursing homes. If the aged subjects are ''healthy'' they may nonetheless have subclinical disease, which can alter outcomes in studies that seek to determine a drug's disposition and effects. However, aged subjects that are truly healthy may represent an elite minority so that the study's results may not be applicable to the general elderly population. Longitudinal studies are almost impossible to complete and data is sparse, but recent findings indicate that the geriatric population is, indeed, heterogeneous.

In addition to these pitfalls, it is not known how generalizations about aging physiology, even if they are true, can be applied to drug disposition, since most drugs have not been subjected to exhaustive age-specific testing and few conclusions can be reached based on pharmacokinetic data. Even less is known about pharmacodynamic changes because the study of age-related tissue receptor density, activity, and sensitivity is in its infancy. We must therefore rely on clinical observations to a large extent when drawing conclusions about efficacy and potential toxicity of various agents in use. The Subcommittee concludes that the results of the usual gavage studies are adequate.

iii. *Irritation and delayed contact sensitization studies in humans.* Observations during adequate clinical studies are sufficient to demonstrate the irritation and sensitization potential of an ingredient or ingredient combination. However, if necessary, a number of methods embodying the use of patch testing have proven of value in determining skin irritancy and systemic sensitization. The Subcommittee recommends one of the following three methods of patch testing to address concerns of irritancy and sensitivity:

• *Draize testing.* In the Draize human skin irritancy and sensitization tests or one of its various modifications (Ref. 55), the testing should be performed on the skin of the subject's back or arm.

• *Method of Shelanski and Shelanski.* In this method (Ref. 56), the active ingredients or the formulation under study are applied at frequent intervals of 1 or 2 days to the test site for 3 or 4 weeks. After a rest period of 2 weeks, a single dose of the drug is applied as a challenge. The preliminary applications are made to detect primary skin irritants and provoke sensitization in susceptible individuals. The challenging dose detects whether or not the drug is a skin sensitizer.

• *Maximization procedure of Kligman.* This procedure (Ref. 57) or one of its modifications uses an irritant applied over a desquamated test site. Desquamation is performed by using a rubbing technique that facilitates penetration, thereby hastening and accentuating the skin-sensitizing potential of the substance. Other validated human models may be used.

iv. *Microbiologic evaluation.* The Subcommittee is concerned about the potential of antigingivitis/antiplaque ingredients with antimicrobial effects to allow emergence of opportunistic pathogens, induce resistance in oral microorganisms, or allow an oral overgrowth of inherently resistant potential pathogens. Representative microbial species and their relative proportion to the total cultivable microflora in supragingival plaque and saliva should be monitored over at least a 6-month period of continuous use of the antiplaque product to determine if a shift in the oral flora has occurred that might result in the proliferation of pathogenic microorganisms, which may include *Candida* species and other yeast, *Staphylococcus aureus* and other *Staphylococcus* species, beta-hemolytic *Streptococci*, and enteric gram-negative rods. Additionally, for those antigingivitis/antiplaque ingredients where the mechanism of action is suspected to be antimicrobial, an assessment of changes in microorganisms associated with gingival disease should be carried out. One determination should be made prior to the start of use, one at the conclusion of the study, and one at an intermediate time. In vitro minimum inhibitory concentrations should be assessed for representative species to determine the development of increased resistance after prolonged antimicrobial therapy.

b. *Effectiveness.* The Subcommittee's determination of the therapeutic effectiveness of ingredients and combinations of ingredients for antigingivitis/antiplaque use is based on published and unpublished studies containing pharmacological data considered by the Subcommittee to be scientifically valid and pertinent. Clinical criteria for proof of effectiveness of a single ingredient or combination of ingredients were determined by evaluating data from valid controlled studies and by calling on the clinical expertise of the

Subcommittee members. Proof of effectiveness of a single ingredient or combination of ingredients was determined by evaluating data from valid, well-controlled studies demonstrating a significant reduction of the symptoms or a therapeutic benefit for the stated indication in the labeling.

Although the OTC drug review is an active ingredient review, not a product review, the Subcommittee recognizes that a final product must be formulated properly, according to accepted pharmaceutical manufacturing practices. If a product is not formulated properly, active ingredients may be present in less than the minimum effective dose, may be in a form that does not exert the intended therapeutic effect(s), or may not be bioavailable. Therefore, the Subcommittee considered it important whether or not inert ingredients or other active ingredients in a formulation might alter the effect of the product's principal active ingredient. The designation of a pharmaceutical necessity as an inactive ingredient does not necessarily mean that the ingredient is pharmacologically inactive.

The Subcommittee considers its recommended ''points to consider'' acceptable current approaches for arriving at valid conclusions concerning the effectiveness of OTC antigingivitis/antiplaque drug products. These ''points to consider'' do not preclude the use of newer, more refined laboratory or clinical techniques to establish effectiveness.

c. Clinical trials. Acceptable studies should state the specific objectives of the study, a review of pertinent literature, and present the scientific rationale for the use of the ingredient. The mode, frequency, and duration of application should be thoroughly described. The indices and variables selected for measuring effectiveness, the methods of measurement, and the rationale for such choices should be characterized. The Subcommittee believes that the effectiveness of an OTC antigingivitis ingredient, antigingivitis/antiplaque ingredient, or ingredient combination should be demonstrated by evidence of a clinically significant endpoint, specifically a reduction and/or prevention of gingivitis. In general, the Subcommittee would also expect a reduction of dental plaque mass and/or plaque virulence (degree of pathogenicity as indicated by the severity of the disease produced). However, the Subcommittee also believes that an ingredient can reduce gingivitis without a demonstrated reduction of plaque. Where possible, additional evidence for the effectiveness of the agent should be provided by demonstrating a shift in the plaque flora.

i. *Design*. Studies should measure the difference between reduction or prevention of dental plaque and gingivitis resulting from the test ingredient as compared to a placebo. Examples of acceptable experimental designs include crossover, parallel, factorial, sequential, single-blind, and therapeutic equivalency studies. Preference should be given to using double-blind studies with a placebo control. The placebo is the formulation of the test agent without the active ingredient, or some other suitable placebo.

ii. *Subjects*. A sufficient number of subjects should be used to permit statistical analysis for the data obtained. The number of subjects tested should be sufficient to eliminate examiner bias and bias introduced by the placebo effect, if applicable, and to allow for anticipated dropouts and estimated variability of effect. The subjects should be of both genders and within the age groups for which the active ingredient is intended. Specific exclusionary criteria should be given.

iii. *Conduct of the study*. The study should be of sufficient duration to demonstrate effectiveness. The duration will depend upon the actual use, anticipated effect, potential sustained benefits, and any safety considerations. The Subcommittee believes that such studies should be at least 6 months in duration to provide sufficient time for an ingredient to exert an antigingivitis/antiplaque effect and for adverse events to manifest themselves. Six months will also provide time to investigate the possibility that an OTC oral ingredient used daily over an extended period of time might cause a shift in the oral flora that may result in the proliferation of pathogenic microorganisms. Scoring and oral health evaluations should be done at baseline, at completion, and at appropriate intervals during the study. Baseline demographic, medical, historical, and physical data for each subject should be obtained and recorded. Such data should include a medical history, a complete oral examination, laboratory studies, if indicated, and other pertinent data.

The treatments should be performed on a random basis. The randomization procedure should be used so that variables not otherwise controlled balance out. The number and frequency of applications of the preparation should be in accordance with the method outlined in the indication for use and directions in the labeling. The clinical investigative team should monitor subjects during the study to detect any adverse events and take appropriate action. An evaluation of dose response and possible mechanism of action would enhance any submission.

iv. *Appropriate assessments*. Appropriate assessments using validated or accepted techniques must be used.

v. *Interpretation of data*. Investigative methods should be described in sufficient detail so that experiments can be repeated by another investigator to verify and confirm results. Methods of statistical analysis should be determined before starting the study.

Positive evidence of effectiveness should be obtained from a minimum of two studies, each conducted by an independent investigative group. In addition to statistical significance, clinical importance should be addressed. Strength of effect and concern about statistically significant changes not being clinically significant reflect the importance of randomized controlled trials of longer duration to determine if individuals benefit from proposed agents and interventions. Statistical significance can be easily calculated using a nominal (categorical) scale such as gingival index scores. A large ''N'' offers scores with an approximately normal distribution so that parametric statistics can be used, as if using exact measures such as in an interval or ratio scale. The gingival index, however, is a nominal scale and the difference between 0 and 2 is not the same as the difference between 1 and 3. Slight differences exist in mean gingival index scores which are not clinically obvious and cannot be easily discerned in a subject. A product can produce a change in the response variable that is statistically significant, yet the question of clinical significance remains unanswered.

III. Classification of Active Ingredients

In addition to carefully reviewing the submitted data, the Subcommittee considered all pertinent data and information available in arriving at its conclusions and recommendations regarding the active ingredients. The following tables summarize the Subcommittee's recommended categorization of active ingredients:

TABLE 2.—CATEGORIZATION OF SINGLE ACTIVE INGREDIENTS

Active Ingredients	Safety	Efficacy
Aloe vera	III	III

TABLE 2.—CATEGORIZATION OF SINGLE ACTIVE INGREDIENTS—Continued

Active Ingredients	Safety	Efficacy
Cetylpyridinium chloride	I	I
Dicalcium phosphate dihydrate	I	III
Hydrogen peroxide	I	III
Sanguinaria extract	I	III
Sodium bicarbonate	I	III
Sodium lauryl sulfate	I	III
Stannous fluoride (for gingivitis)	I	I
Zinc citrate	I	III

TABLE 3.—CATEGORIZATION OF COMBINATIONS OF ACTIVE INGREDIENTS

Active Ingredient Combination	Safety	Efficacy
Alkyl dimethyl amine oxide and alkyl dimethyl glycine	III	III
Eucalyptol, menthol, methyl salicylate, and thymol	I	I
Hydrogen peroxide and povidone iodine	III	III
Hydrogen peroxide and sodium bicarbonate	I	III
Hydrogen peroxide, sodium citrate, sodium lauryl sulfate, and zinc chloride	I	III
Peppermint oil and sage oil	I	III
Polydimethylsiloxane and poloxamer	I	III
Stannous pyrophosphate and zinc citrate	I	III

A. Category I Conditions

The Subcommittee recommends Category I labeling for all Category I single antigingivitis/antiplaque active ingredients and combinations of active ingredients (see section II.D of this document).

1. Category I Single Active Ingredients

Cetylpyridinium chloride (rinse)
Stannous fluoride (dentifrice)

a. *Cetylpyridinium chloride (rinse).* The Subcommittee concludes that cetylpyridinium chloride at concentrations of 0.045 to 0.1 percent with at least 72 to 77 percent chemically available cetylpyridinium chloride is safe and effective for use in mouthrinse formulations as an OTC antigingivitis/antiplaque agent. Cetylpyridinium-containing mouthrinses have been used in the United States since 1940. Cetylpyridinium chloride 0.025 percent to 0.1 percent has been marketed nationally in several products. Products containing cetylpyridinium chloride have also been marketed internationally. The more than 55-year U.S. marketing history is significant with respect to the ingredient's safety.

Cetylpyridinium chloride is a quaternary nitrogenous compound l-hexa-decyl pyridinium chloride with antimicrobial activity against many microorganisms, including viruses. Its chemical and physical properties are well described in the USP (Ref. 58). It is classified as a cationic surface-active agent and contains a cetyl radical substituted for hydrogen atom on position 1. In hydrochloric acid it forms a chloride salt. The cetyl radical renders the molecule lipophilic, contributing to the lipophilic/hydrophilic balance which is necessary for the antimicrobial activity of such quaternary nitrogenous compounds. The antimicrobial activity is dependent upon the positioning of the charged molecule with bacterial cells that carry a net negative charge. This positioning allows the hydrophilic portion of the cetylpyridinium chloride to interact with the cell membrane, resulting in leakage of cellular components, disruption of cellular metabolism, inhibition of cell growth, and cell death (Refs. 59 through 62). Because the positively charged hydrophilic region is critical to antimicrobial activity, any formulation that diminishes the activity of this cationic group or that competes with this group may inactivate the product. Therefore, it is essential to establish that the cetylpyridinium chloride in products is sufficiently biologically active to justify an antigingivitis claim.

i. *Safety.* The Subcommittee believes there are sufficient safety data to permit final classification of the safety of cetylpyridinium chloride as an OTC antimicrobial agent for topical use in the oral cavity when used within the proposed dosage limits set forth below. The Subcommittee bases its conclusions on the safety of cetylpyridinium chloride mouthrinses used in animal and pharmacokinetic studies, assessment of adverse events in randomized, placebo-controlled clinical trials, and postmarket spontaneous adverse event data reported to the manufacturer and FDA.

The LD_{50} of cetylpyridinium chloride is 250 milligrams per kilogram (mg/kg) given subcutaneously, 6 mg/kg intraperitoneally, 30 mg/kg intravenously, and 200 mg/kg given orally as a pure compound (Ref. 63). The data (Ref. 64) show that the oral LD_{50} values in the rat from a mouthrinse containing 0.05 percent cetylpyridinium chloride were 34 mg/kg to 48 mg/kg of the mouthrinse alone. This lower LD_{50} with the rinse formulation as compared to cetylpyridinium chloride in solution is likely due to the other components of the mouthrinse, such as the alcohol.

Subchronic toxicity studies of cetylpyridinium chloride administered orally at dose levels ranging from 5 to 500 mg/kg showed morbidity and death at 125, 250, and 500 mg/kg. At lower doses, the only significant finding in rats and dogs was gastric irritation at doses of 50 mg/kg per day and higher (Ref. 65). These studies are similar to studies conducted prior to 1950.

Two chronic exposure safety studies of 6 months and 1 year were reported (Ref. 65). Doses administered daily by oral gavage ranged from 5 to 75 mg/kg. Significant decreases in body weight and weight gain were noted in 40- and 75-mg/kg animals of both sexes. At necropsy, GI irritation was manifested as thickening of the stomach mucosa observed at the 40- and 75-mg/kg level, and in some animals administered 15 mg/kg.

Local irritation studies (Ref. 65) included eye irritation tests and dermal exposure. Evidence of eye irritation was observed at high concentrations but no dermal lesions were observed. Local irritation using cetylpyridinium chloride mouthrinse formulations was assessed in the canine oral mucosa irritation model (Ref. 65). A cotton plug saturated with cetylpyridinium chloride mouthrinse was applied to the gingival mucosa three to five times a day for 4 days. Mouthrinse formulations containing up to 0.45 percent cetylpyridinium chloride did not induce irritation after 20 applications. Lin et al. (Ref. 66) evaluated inhalation toxicity in rats and found clinical signs of toxicity, including respiratory difficulty, eye irritation, and nasal discharge at concentrations of approximately 0.1 mg cetylpyridinium chloride/liter and above. However, these nonlethal effects were reversible.

A study of the effects of alcohol and cetylpyridinium chloride on the buccal mucosa of hamsters was reported (Ref. 67). Animals received daily applications of 0.05 percent cetylpyridinium

chloride for 21 days on the everted hamster cheek pouch. Abrasion was also carried out. No significant differences were found between the control and study animals.

Contact sensitization potential was assessed using a 25-percent concentration of cetylpyridinium chloride in petrolatum for sensitization and a 10-percent concentration for challenge. No evidence of sensitization was observed in any of the 24 participants (Ref. 65).

Pharmacokinetic studies assessing absorption, distribution, and elimination of cetylpyridinium chloride were done in rats and dogs (Ref. 65). In the rat study, approximately 85 percent of a single dose of radiolabeled cetylpyridinium chloride was detected in the feces and about 10 percent in the urine. The dog study was inconclusive, since only 56.5 percent of the radiolabeled cetylpyridinium chloride administered was recovered from the urine, feces, case rinses, organs, and carcass.

The safety data were systematically collected from several clinical trials (Refs. 68, 69, and 70). Adverse events did not differ between placebo and control except for tongue and tooth discoloration associated with cetylpyridinium chloride. In contrast, Lobene et al. (Ref. 71) found that approximately a quarter of the subjects using cetylpyridinium chloride reported a slight, transient irritation of the gingiva. In one short-term study (Ref. 72), more subjects in the cetylpyridinium chloride group were found to have aphthous ulcers than the placebo group. Gingival irritation and aphthous ulcers were not reported in other randomized controlled clinical trials of cetylpyridinium chloride-containing mouthrinses. Further studies of the mucosal irritancy potential of cetylpyridinium chloride, especially in those with hyposalivation, are warranted.

Studies (Refs. 65 and 73) showed that there are no significant changes in the balance of the human oral flora or in the overgrowth of potential pathogens such as *Candida*. It appears that cetylpyridinium chloride has activity in the range of 0.12 to 8 micrograms per milliliter (μg/mL) in vitro against *S. aureus*, *S. sanguis*, *E. corrodens*, *Neisseria*, *Veillonella parvula*, *P. gingivalis*, *F. nucleatum*, and *Candida albicans*.

Data on teratogenic and mutagenic effects are available from in vitro and in vivo animal studies (Ref. 65). However, long-term cumulative effects on metabolism and teratogenic effects are not available from controlled human studies. The FDA spontaneous adverse reaction reports and adverse events reports submitted suggest that clinical experience following long-term OTC use of the ingredient has not revealed overt toxic manifestations. Although the summarized FDA spontaneous adverse drug reaction report (Ref. 65) indicates that three deaths and six comas occurred after ingestion of cetylpyridinium chloride-containing mouthrinses, it is unclear to what extent the mouthrinses or other circumstances may have contributed to these severe adverse events. The Subcommittee notes that tooth and tongue staining, as well as oral irritation, may occur with the use of products containing cetylpyridinium chloride.

In summary, the safety of cetylpyridinium chloride has been extensively evaluated in a variety of controlled, clinical and nonclinical studies. Based on this information, in addition to adverse event data collected during more than 55 years of U.S. marketing of mouthrinses containing cetylpyridinium chloride, the Subcommittee concludes that cetylpyridinium chloride is safe when used at concentrations of 0.045 percent to 0.1 percent in mouthrinse formulations.

ii. *Effectiveness*. The Subcommittee concludes that cetylpyridinium chloride is effective as an OTC antigingivitis/antiplaque ingredient within the dosage limits proposed above.

The Subcommittee evaluated six placebo-controlled, blinded, clinical efficacy trials (Ref. 65). In five of the six studies, a 15- to 27-percent reduction in supragingival plaque was obtained with cetylpyridinium chloride in concentrations ranging from 0.05 to 0.1 percent. The reduction seems to persist for 6 months. Four 6-month trials and several shorter trials were also submitted (Refs. 70 and 73). All of the studies demonstrated a significant reduction of supragingival dental plaque with the use of 0.045 to 0.1 percent cetylpyridinium chloride mouthrinse. This is a reproducible finding in both short-term and 6-month studies based on the data submitted and in the published literature (Ref. 74).

The results of two 6-month studies (Refs. 68 and 69), a 2-month study (Ref. 75), and a 4-month study (Ref. 76) showed reductions in gingivitis (based upon gingival index) ranging from 15.7 to 41 percent. Although trends were noted, no clear-cut dose response in the antigingivitis effect was documented in any one study in that range.

Data from four other 6-month studies (Ref. 70) (three of which were carried out by different research groups) did not demonstrate a statistically significant reduction in gingivitis. In the Ciancio study (Ref. 77), there was no statistically significant reduction in gingivitis, although there was a reduction in plaque. Similarly, in the Lobene study (Ref. 78), no differences in gingival index were seen at 4, 20, or 26 weeks, although there was a statistically significant reduction in gingival index at 8 weeks. In two studies (012-035 and 012-037) by Ackerman and DeGenero (Ref. 79), a mouthrinse containing cetylpyridinium chloride showed no effect on gingivitis at 6 months. In a 6-week study by Moran (Ref. 80), cetylpyridinium chloride in a mouthrinse had no effect on plaque or gingivitis. Although most of the formulations reduced plaque, the gingivitis results in these studies are not consistent.

The Subcommittee believes that differences in the results of studies on the effectiveness of cetylpyridinium chloride mouthrinse are likely explained by the use of different formulations (Refs. 65, 70, and 81). Based on the data presented, the biological effectiveness and chemical availability of cetylpyridinium chloride in a mouthrinse appear to be greatly affected by the particular formulation. Cetylpyridinium chloride in mouthrinse formulations all at approximately 0.045 percent nominal concentrations were shown to vary markedly between 4 and 77 percent. Thus, it is clear that inactivation of cetylpyridinium chloride is likely based upon formulation. It is recommended that the bioavailability of cetylpyridinium chloride in each formulation be determined to reduce the possibility that the active ingredient is removed due to chemical reaction, complexing, micelle (a colloid particle formed by an aggregation of small molecules) formation, or other sources of deactivation. Assessment of mouthrinses containing cetylpyridinium chloride in formulations similar to those tested in the positive studies (Refs. 68, 69, 76, and 77) show that 72 to 76 percent of the cetylpyridinium chloride is available (Ref. 82). Therefore, it is reasonable to assume that formulations containing 72 to 76 percent available cetylpyridinium chloride are active in reducing gingivitis and plaque.

At the request of the Subcommittee, the manufacturer conducted additional analyses demonstrating the effectiveness of cetylpyridinium chloride on a site and subject basis, relative to other oral healthcare practices, and on the basis of odds-ratio calculations. Specifically, using a minimum 33 percent reduction in bleeding criterion, results of 4 long-term studies were pooled to estimate an

overall odds ratio for improvement relative to a placebo. After 3 months of product use, the odds ratio was 3.12 with a 95 percent confidence interval of 2.85 to 3.40. After 6 months, the odds ratio was 3.10 with a 95 percent confidence interval of 2.75 to 3.45. Based on the totality of the data, the Subcommittee concludes that cetylpyridinium chloride mouthrinse is safe and effective as an OTC antigingivitis/antiplaque agent.

b. *Stannous fluoride (dentifrice).* The Subcommittee concludes that stannous fluoride in a compatible dentifrice base at a concentration of 0.454 percent is safe and effective for OTC use as an antigingivitis active ingredient.

i. *Safety.* Stannous fluoride has been used as an OTC caries-preventive agent in toothpastes in the United States since 1954. Since 1981, it has been largely replaced by sodium fluoride or sodium monofluorophosphate. However, during this 27-year period, it is estimated that at least 70 billion doses of stannous fluoride were sold in the United States. Thus, a long market history exists to support its safety.

The toxicity of ingesting fluoride from toothpaste has been reviewed extensively (Ref. 83). Concern has been expressed over the need to supervise the use of fluoridated toothpaste by young children because of the potential risk of developing fluorosis (Ref. 84). Acute toxicity of stannous fluoride in the rat (LD_{50}) appears to range from 31 to 300 mg/kg. Thus, it appears to have an acute toxicity comparable to that of sodium fluoride (Refs. 85 and 86). Toxicity studies show that a dentifrice formulation containing stannous fluoride plus stannous chloride was comparable to other nationally marketed fluoride-containing dentifrices.

Several subchronic toxicity tests of stannous fluoride dentifrice formulations have been carried out (Ref. 85). In a study conducted over 3 months, rats received either 3.3 grams (g) dentifrice/kg/daily (= 13.2 mg of stannous fluoride/kg/daily) or 8.4 g dentifrice/kg/daily (= 33.6 mg of stannous fluoride/kg/daily) by gavage. Any observed effects were not attributed to stannous fluoride. Two additional 91-day studies were conducted in rats. Dentifrice slurries in distilled water were administered by gavage. All dentifrice groups revealed microscopic alterations in the stomach lining, such as eosinophilic gastritis, squamous epithelial hyperplasia, and squamous vacualization. No other abnormalities were observed. No tumorigenic effects have been reported from studies conducted in male or female rats or mice. Studies conducted in human volunteers who received 50 mg a day of the stannous ion as stannous chloride revealed that about 3 percent of the dose is absorbed.

Based on results from a 13-week oral toxicity study in rats on stannous chloride conducted through the National Toxicology Program (NTP), a safety factor of 5,000 exists for potential exposure to stannous salts from use of a dentifrice containing 0.454 percent stannous fluoride. The safety factor is defined as the ratio between no observed adverse effect level (NOAEL) in the NTP study and the anticipated exposure to stannous salts from twice daily use of stannous fluoride toothpaste.

The Subcommittee's analyses of clinical studies, including detailed examination of soft tissue and microbiological assays, revealed no adverse shifts among the oral microbiological populations studied, no overgrowth of opportunistic pathogens, and no development of oral microbial resistance to stannous fluoride. Significant reductions in *S. mutans* were observed among subjects exhibiting higher levels of this organism. Based on these data, the Subcommittee concludes that a 0.454 percent stannous fluoride dentifrice is safe for long-term use.

Stannous ion in stannous fluoride dentifrices has been associated with staining of tooth surfaces, which in some instances may be severe (Refs. 87 and 88). In studies CC–191, CC–238, and CC–247 (Ref. 89), 2.1 percent of subjects discontinued the trial due to self-perceived tooth staining. Oral desquamation was reported by five subjects using a stannous fluoride dentifrice. This adverse effect does not appear to be an extensive problem because persons with hyposalivation have used stannous fluoride gels without adverse effects.

Because staining is a common phenomenon with the use of stannous fluoride, the Subcommittee evaluated data concerning the extent of consumer sensitivity to dental staining and the ease with which these stains can be removed. Studies demonstrated that dental staining with 0.454 percent stannous fluoride was noticed by a minority of consumers and that staining can be removed from enamel surfaces and dental restorations during conventional prophylactic procedures. However, the Subcommittee recommends that product labeling include a restriction on use by children and a statement concerning the likelihood of tooth staining.

ii. *Effectiveness.* Stannous fluoride has been incorporated into numerous dentifrice formulations that contain a variety of abrasive substances, including hydrated silica gels, calcium pyrophosphate, and a variety of excipient agents (*see* the **Federal Register** of March 28, 1980, 45 FR 20666 at 20684 to 20688).

The careful formulation of stannous fluoride dentifrices to prevent rapid oxidation and hydrolysis, and thereby inactivation, of stannous ions is critical for clinical effectiveness of these dentifrices. Oxidation can be prevented in several ways. In one approach, water is excluded from the formulation. Another approach involves use of chelating agents such as pyrophosphate, citrate, gluconate, gantrez (a copolymer of maleic acid and methyl ether) or phytate, which form soluble stannous complexes. In addition, incorporation of another stannous compound, such as stannous pyrophosphate or stannous chloride, provides a steady-state situation in which the concentration of bioavailable stannous fluoride is relatively stable. It is essential to note that the inclusion of stannous fluoride alone in a dentifrice without stabilization is not sufficient to obtain optimum clinical effectiveness. Clearly, products containing stannous fluoride may have a defined shelf life.

Stannous fluoride has a long and well-established history as a caries-preventive agent (Ref. 90). Stannous fluoride at a 0.4-percent concentration results in a concentration of 970 parts per million (ppm) fluoride (Ref. 86). Effects of stannous fluoride on plaque formation and gingivitis have given mixed results which, in part, reflect the duration of the studies, the concentration used, and the type of subjects studied.

The Subcommittee evaluated the results of three primary trials and three supportive trials (Refs. 85 and 89) of a stabilized 0.454-percent stannous fluoride dentifrice for antiplaque and antigingivitis claims. Two of the primary 6-month trials (CC–191 and CC–238) carried out in Indiana had results that are consistent with each other (Ref. 89). The final assessments were consistent with the interim 3-month assessments. The third study (CC–247), conducted in Northfield, lasted for 7 months and had results that appeared to differ in some measures from those in Indiana (Ref. 89). The Indiana studies had reductions of 18.8 percent and 20.5 percent in gingival index, 30.5 percent and 33.4 percent in bleeding index, and a nonsignificant reduction of 2.6 percent and 3.1 percent compared with placebo in plaque. In contrast, the Northfield study (one evaluator) reported a 10.7-percent

reduction in gingivitis in the stannous fluoride group and a statistically not significant 6.6-percent increase in the bleeding index. There was a 17.8-percent reduction in a Turesky modified Quigley-Hein Plaque Index and a 1.1-percent reduction using the Silness & Loe Plaque Index system. Two graders were used in this study, and they obtained large numerical differences in their assessments at the 3-month assessment period and the final 7-month assessment. No significant shifts in the microbial flora were reported after 3 and 6 months of product use.

Three supportive double-blind and independent studies (CC–174, CC–178, and CC–205) have been reported (Ref. 91). Two studies (CC–174 and CC–178) continued for 6 months and the third study (CC–205) for 2 months. Study CC–174 demonstrated statistically significant differences in the indices from the stannous fluoride group compared with the negative control at the 1.5- and 3-month grading periods. However, all indices were not significant at the 7-month grading period.

Study CC–178 (Ref. 91) revealed no significant differences in the gingival, bleeding, and plaque indices after 2 months use in the stannous fluoride group, compared with the control. After 6 months use, there was a statistically significant difference in the gingivitis index (9.3 percent) in the stannous fluoride group. Significant differences were not detected in the bleeding and plaque indices among the two groups.

Study CC–205 (Ref. 91), which was conducted for 2 months only, revealed a significant difference (15.4 percent) in the gingivitis index of the stannous fluoride group compared with the control. There was a reported 23.9 percent difference in the bleeding index. However, the scores for both groups were exceptionally low compared with all of the study groups. Statistically significant differences in plaque scores among the groups were not detected.

In five of the six studies reported, no significant differences in plaque scores were observed at the end of the evaluation period in subjects using stannous fluoride dentifrices compared with those using a control dentifrice. In 7 of 12 exams in two of the six studies, there was a reported statistically significant reduction in bleeding scores, and in five of the six studies there was a reduction in gingivitis scores associated with the use of stannous fluoride dentifrices.

The Subcommittee evaluated additional information on the effectiveness of a 0.454 percent stannous fluoride dentifrice, including additional analyses it requested. The results of these analyses helped to establish that the study populations were appropriate for the OTC gingivitis indication recommended by the Subcommittee. Disease levels in the populations used in clinical studies supporting the stannous fluoride dentifrice were only slightly higher than disease levels established in published epidemiological studies and in surveys of oral health status conducted by the National Institute of Dental Research.

Additional data were presented concerning the clinical relevance of the observed beneficial effects of the dentifrice on gingivitis. These data included site-specific analyses demonstrating that a 0.454 percent stannous fluoride dentifrice provided uniform efficacy in reducing gingivitis across the dentition and, in particular, in regions of significant disease. This site-based analysis was further expanded to compare treatment effects (*e.g.,* causing a bleeding site to become a nonbleeding site) with benefits in preventing new disease (*e.g.,* preventing a nonbleeding site from becoming a new bleeding site) during clinical studies. These analyses revealed that, compared to placebo, the stannous fluoride dentifrice was beneficial in preventing and reducing gingivitis and gingival bleeding.

An analysis of the clinical benefits of stannous fluoride in reducing gingivitis compared to increased brushing, flossing, and frequent visits to a dentist indicated that a stannous fluoride dentifrice provides benefits comparable to the improvements observed from these established dental hygiene procedures.

Finally, odds ratio analyses were used to determine the likelihood of an individual deriving a benefit from the use of a stannous fluoride dentifrice. Based on the benefits achieved from dental hygiene and benefits seen in studies CC–191 and CC–238 (Ref. 89), a meaningful benefit for a subject was defined as at least a 33-percent reduction in bleeding. Using this definition, the results of five long-term studies (Refs. 89 and 91) were pooled to estimate an overall odds ratio for improvement relative to a sodium fluoride control. After 3 months of use, the odds ratio was 1.57 with a 95-percent confidence interval of 1.29 to 1.85.

A review of the cited literature indicates that a number of studies examined the effects of stannous fluoride in gels, mouthrinses, and dentifrices. Many of these studies were of short duration, used few subjects, or used special groups of subjects. Thus, the quality and relevance of the data are, in some instances, questionable. The results are far from uniform in showing benefits from the use of stannous fluoride.

With the exception of the studies submitted by the sponsor, there appear to be few studies involving the use of dentifrices containing stannous fluoride. Ogaard *et al.* (Ref. 92) studied the effect of a stannous fluoride dentifrice on plaque regrowth in 15 subjects for 24 hours and 21 subjects for 3 weeks using a crossover design. Stannous fluoride was compared to a sodium monofluorophosphate dentifrice and a dentifrice without fluoride. Stannous fluoride gave significantly lower regrowth values than monofluorophosphate or placebo.

In the 3-week crossover study (Ref. 92), 21 orthodontic subjects brushed twice daily for 1 minute with a stannous fluoride dentifrice or placebo paste. Less plaque was observed in the stannous fluoride group when the orthodontic brackets were 1 to 5 millimeters (mm) from the gingiva; if the brackets were closer, there was no difference in the effects of the stannous fluoride and the placebo dentifrice. No significant improvement was observed in gingival health regardless of treatment group.

Bay and Rolla (Ref. 93) conducted a double-blind, crossover study in 40 pupils aged 15 years to compare the effects of a stannous fluoride dentifrice and a placebo dentifrice without stannous fluoride. The number of times the dentifrice was used was not stated, and the gender of the pupils was not disclosed. The study continued for 4 weeks. There was reduced plaque formation in the stannous fluoride group and a small reduction in gingival index.

Svatun (Ref. 94) compared the effect of dentifrices containing: (1) 0.4 percent stannous fluoride, (2) a similar dentifrice without stannous fluoride, (3) 0.4 percent stannous fluoride plus stannous pyrophosphate, and (4) 0.8 percent chlorhexidine gel. Twelve female dental students were included and tests lasted for 4 days. The test products were placed in cap splints that covered the teeth only and held in place for 2 minutes twice daily. Subjects rinsed with sucrose (15 percent) for 1 minute every other hour to enhance plaque formation. No mechanical oral hygiene was allowed during the study. The dentifrice containing 0.4 percent stannous fluoride plus stannous pyrophosphate gave significantly lower plaque scores than the dentifrice containing 0.4 percent stannous fluoride alone, or a similar dentifrice without stannous fluoride. There was a wide

range in scores among subjects using the dentifrice containing 0.4 percent stannous fluoride plus stannous pyrophosphate.

In a second study in the same report (Ref. 94), Svatun examined the influence of polishing teeth with a stannous fluoride or sodium monofluorophosphate dentifrice on 24-hour plaque regrowth in 8 mentally retarded home care subjects. Oral hygiene was suspended for 24 hours. There was less plaque regrowth following the stannous fluoride treatment, confirming the results of previous studies showing the effectiveness of stannous fluoride as a plaque inhibiter. A cap splint pilot study comparing stannous fluoride and sodium monofluorophosphate dentifrices did not result in any improvement in the gingiva of these subjects.

Several studies have been carried out using rinses or gels containing stannous fluoride. It is doubtful whether the results from these studies are strictly applicable to dentifrices containing stannous fluoride. Nevertheless, the data are worth exploring because they may help to clarify the therapeutic potential of stannous fluoride.

Svatun (Ref. 95) compared the plaque-inhibiting effects of mouthrinses containing 0.2 and 0.3 percent stannous fluoride, 0.1 percent chlorhexidine, and distilled water randomly distributed among 12 dental hygienist students. Subjects rinsed with 10 mL for 1 minute twice a day for 4 days, with no other oral hygiene permitted. Plaque index scores were brought to 0 at the beginning of each test period. Mean plaque scores were 0.35 for 0.2-percent stannous fluoride, 0.20 for 0.3-percent stannous fluoride, 0.12 for chlorhexidine, and 1.02 for the placebo. A long-term study (Ref. 95) in another group of 5 students showed that the effect of a 0.3-percent stannous fluoride mouthrinse could be maintained for 3 weeks.

Klock *et al.* (Ref. 96) compared the effects of rinsing with stannous fluoride or sodium fluoride (200 ppm fluoride) twice daily for 2 years on oral health in adults. Thirty-seven subjects started the study; 15 withdrew during the first year and 3 withdrew during the second year. After 2 years, there were 12 in the stannous fluoride group and 7 in the sodium fluoride group, a total of 19 subjects. The authors commented: ''The population of subjects was generally unreliable.'' Plaque scores were not compared among the groups because the values were skewed at the baseline. Both groups showed a reduction in plaque at 1 year and subsequent increase after 2 years. Bleeding sites were significantly reduced after 1 year in the stannous fluoride group. This trend continued into the second year, but the results at 2 years were no longer statistically significant. The lack of statistical significance is probably due to the loss of subjects between the first and second years. Other possible factors are the inability of subjects to comply with the mouthrinsing regimen and the development of bacterial resistance to the stannous fluoride rinse. The stannous fluoride group harbored significantly fewer *S. mutans* than did the sodium fluoride group.

Several studies examining the effects of 0.4-percent stannous fluoride gels have been carried out in persons wearing prosthetic or orthodontic appliances. The validity of extrapolating data from these studies to support clinical claims for 0.4-percent stannous fluoride dentifrice is open to question even though these studies may provide information on the potential therapeutic effect of stannous fluoride.

Derkson and MacEntee (Ref. 97) examined the effects of a 0.4-percent stannous fluoride gel in 17 subjects with overdentures using a double-blind, crossover design. A nonfluoridated gel was used as a control. Each gel was applied daily for 6 months. Gingival and plaque index scores were recorded. A total of 34 teeth in 12 subjects who completed the study were available for assessment. No difference between the effects of two gels was observed in Gingival Bleeding Index scores from subjects who used the stannous fluoride gel first. Subjects who used the placebo first showed a 19-percent reduction in gingival index scores following use of stannous fluoride gel. The plaque index scores did not show any significant difference.

Tinanoff *et al.* (Ref. 98) conducted a double-blind study in 61 adults with fixed or removable dental prostheses. Subjects were given a thorough prophylaxis, including scaling and root planing, and were instructed to brush once daily for 2 weeks with a regular dentifrice. After the 2-week washout period, subjects then brushed twice daily (without rinsing) with a 0.22 percent sodium fluoride gel or 0.4 percent stannous fluoride gel. Subjects were not permitted to have a dental prophylaxis during the course of the study. At the end of 6 months, gingival index scores in the stannous fluoride group, using all teeth (including abutment teeth), were 48 percent lower than in the control group. The authors noted ''increasing change between groups over time in the percent bleeding site scores appears to be due to rise in the number of bleeding sites in the sodium fluoride group during course of the study.'' (There was no reduction in the number of bleeding sites compared with baseline.) Differences in plaque scores were statistically significant only when computed for abutment teeth. The authors noted ''higher baseline plaque index scores in the sodium fluoride group as compared to the stannous fluoride group might in some way influence other clinical or microbial indices.'' The stannous fluoride group harbored 2.5 log fewer *S. mutans* than did the sodium fluoride group.

Two relatively long-term studies of 0.4 percent stannous fluoride gel gave apparently contrasting results. However, the apparent disparity may be a reflection of the type of subjects and the hypothesis studied. Boyd, *et al.* (Ref. 87) monitored the gingival health of 81 adolescents undergoing orthodontic treatment with fixed appliances while investigating the effects of daily brush-on 0.4 percent stannous fluoride gels. One gel contained 98 percent available tin (used twice daily), and the other gel contained 2 percent available tin (used once daily and later twice daily). The control group did not use any gel. Subjects were instructed not to rinse after using the gel. Subjects continued their normal oral hygiene practices. Sites were scored at baseline and at 1, 3, 6, and 9 months after appliances were applied. There was a gradual increase in plaque accumulation from baseline to 9 months in all groups and no statistically significant difference in plaque scores among the groups. The gingival and plaque indices showed similar patterns. However, the percentage of sites with an index greater than 1 was statistically significantly less than observed in other groups. The percentage of sites with a Bleeding Tendency score greater than 1 also followed a similar pattern. Thus, use of stannous fluoride gel was associated with a smaller increase in gingival index and percent Bleeding Tendency compared with controls. However, there was no reduction in the indices compared with baseline.

In a second long-term study, Wolff *et al.* (Ref. 88) studied the effects of 0.4 percent stannous fluoride gel, 0.22 percent sodium fluoride gel, and a fluoride-free placebo gel in three groups of 281 subjects over 18 months. All subjects brushed with a sodium monofluorophosphate dentifrice twice daily. Subjects then used either a stannous fluoride, sodium fluoride, or placebo gel twice daily immediately after brushing with no rinsing for 30 minutes after using gel. Plaque, bleeding, and gingival indices were assessed after 6, 12, and 18 months.

There was no significant difference in the mean plaque index between any of the groups. The gingival index declined in all groups, with no differences detected between groups. No differences were observed among any groups at any time.

Based on the analyses of effectiveness on a site and subject basis compared to other oral health care practices and on odds-ratio calculations conducted on the submitted data, the Subcommittee concludes that, although available clinical data do not show reproducible long-term effects in reducing dental plaque mass, stannous fluoride is safe and effective in a dentifrice at an appropriately formulated concentration of 0.454 percent as an OTC antigingivitis agent.

2. Category I Combinations of Active Ingredients (*See* General Combination Policy in section II.E of this document)

Eucalyptol, menthol, methyl salicylate, and thymol. The Subcommittee concludes that a combination of essential oils consisting of eucalyptol (0.092 percent), menthol (0.042 percent), methyl salicylate (0.060 percent), and thymol (0.064 percent) in a hydroalcoholic vehicle containing 21.6 to 26.9 percent alcohol in a mouthrinse is safe and effective as an OTC antigingivitis/antiplaque agent.

a. *Safety*. Eucalyptol is a volatile oil prepared by steam distillation of the fresh leaves of *Eucalyptus globulus*. Eucalyptol is colorless, or a pale yellow volatile liquid with a characteristic aromatic, somewhat camphoraceous odor, and a spicy and cooling taste. Eucalyptol is also known as cineol, cineolcayeptol, and cajuptol. It is insoluble in water, but it is miscible with alcohol, chloroform, and ether.

The Dental Panel concluded that eucalyptol is safe as an OTC anesthetic/analgesic active ingredient for topical use on the mucous membranes of the mouth and throat when used at a concentration of 0.025 to 0.1 percent in the form of a rinse, mouthwash, gargle, or spray (47 FR 22712 at 22826, May 25, 1982). It was reviewed and found safe by the Flavor and Extract Manufacturer's Association of the United States (FEMA) (Ref. 99).

Menthol is a secondary alcohol extract from peppermint oil or made synthetically. Chemically, it is also known as hexahydrothymol and 3–paramenthanol. Menthol may be made synthetically by the hydrogenation (reduction) of thymol. The Dental Panel concluded that menthol is safe as an OTC active ingredient for topical use on the mucous membranes of the mouth and throat at a concentration of 0.04 to 2.0 percent in the form of a rinse (47 FR 22712 at 22813). Menthol was reviewed and found safe by FEMA (Ref. 100).

Methyl salicylate is the methyl ester of salicylic acid. Prior to the discovery of a method for chemical synthesis of methyl salicylate, it was produced by steam distillation from natural sources. The natural-source products are known as gaultheria oils, betula oil, sweet birch oil, teaberry oil, and wintergreen oil. Today, these names are used synonymously with methyl salicylate. Methyl salicylate is prepared synthetically by esterifying salicylic acid with methanol. The Dental Panel concluded that methyl salicylate is safe for topical use on the mucous membranes of the mouth and throat when used within the proposed dosage limit up to a 0.4-percent concentration in the form of a rinse, mouthwash, gargle, or spray, not more than three to four times daily (47 FR 22712 at 22828). Methyl salicylate was reviewed and found safe by FEMA (Ref. 101).

Thymol, also known as thyme camphor, is 5-methy-2-isopropyl-2-phenol. It may be prepared synthetically or obtained from volatile oils distilled from *Thymus vulgans* and other related plant sources. Thymol is an alkyl derivative of phenol and has bactericidal and fungicidal properties. It was reviewed and found safe by the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products (the Dental Panel) (47 FR 22712 at 22829, May 25, 1982) and by FEMA (Ref. 102).

The safety of the combination of the four ingredients has been assessed in numerous long-term clinical studies. These studies showed no clinical pathologic change or adverse reactions (Refs. 103, 104, and 105).

Because OTC drug products are readily available, the determination of the safety of single ingredients and combinations of ingredients also requires consideration of possible abuse. Exaggerated use studies have been done. In one study (Ref. 106), 47 healthy adult subjects screened for sensitivity and allergy histories rinsed with 20 mL of the combination of essential oils for 30 seconds under supervision at 5 hourly intervals each day for 5 days and repeated 18 days later for 1 day. No subject developed any oral mucosal lesions attributable to the test product. A second study (Ref. 107) of 45 adult subjects followed a similar protocol. One subject had erythema (2-centimeter lesion) and epithelial sloughing on day 5 of the irritation phase of the study. In a third exaggerated use study involving 18 xerostomic (dryness of the mouth from salivary gland dysfunction) adults, 2 subjects experienced what was described as ''utransient mucosal sloughing'' and continued the regimen. The remaining xerostomic subjects did not develop mucosal lesions (Ref. 108). These studies showed that the potential for mucosal irritation is minimal when these ingredients are used according to label directions.

Two studies evaluated possible shifts in oral microbial populations and the emergence of opportunistic organisms or potential pathogens. One study in 83 subjects (Ref. 109) showed analysis of plaque samples from active agent and control groups. There were no significant increase in presumptive oral pathogens, spirochetes, black-pigmented Bacteroides, *S. mutans*, or *C. albicans*. A second 6-month study (Ref. 110) examined plaque at 3 and 6 months. Three microbiological approaches were used: (1) Microscopic enumeration of cocci, motile and nonmotile rods, and spirochetes, (2) recovery on selective and nonselective culture media, and (3) enumeration by colony morphology on a nonselective medium. No clinically significant shifts were found in the composition of the flora.

Mutagenicity studies have been reported (Ref. 111). The fixed combination of essential oils did not show mutagenic potential in the Ames test, the Unscheduled DNA Synthesis test, and the Mouse Micronucleus test.

Much of the evidence of the safety of the combination of these ingredients comes from their extensive history of use (well over 100 years) and the low incidence of consumer complaints reported by the manufacturer. The data included an estimate of one adverse reaction report for every 38,700,000 doses of these ingredients sold, which is described as an extremely low rate. The four ingredients in this combination have had a long and safe marketing history which contributes to the Subcommittee's conclusion that the combination is safe when used according to label directions.

b. *Effectiveness*. The Subcommittee evaluated seven 6-month, randomized, controlled trials of the effectiveness of a fixed combination of eucalyptol (0.092 percent), menthol (0.042 percent), methyl salicylate (0.060 percent), and thymol (0.064 percent) in a hydroalcoholic vehicle containing 21.6 to 26.9-percent ethyl alcohol. One study was a 6-month, randomized, controlled study (Ref. 103) involving 145 students and staff at an East Coast university, aged 18 to 54 years, randomized into three groups using either the above fixed combination, a vehicle control (a 26.9-percent hydroalcoholic vehicle containing all the ingredients in the test

product except the essential oils), or a water control. Of the 145 subjects who entered the study, approximately 62 percent were male and 20 percent were smokers. Inclusion criteria were 20 natural teeth exclusive of large carious lesions, orthodontically banded, fully crowned, abutment, and third molar teeth, and a minimum score of 2.0 using a modified Loe-Silness Gingival Index plus a minimum score of 1.8 using the Turesky modification of the Quigley-Hein Plaque Index. Of 129 subjects completing the study, 45 were in the essential oils group (mean age 26.1 years), 43 were in the vehicle control group (mean age 27.9 years), and 41 were in the water control group (mean age 24.7 years).

Subjects were supervised as they rinsed twice daily from Monday to Friday with 20 mL for 30 seconds. Coded 3-ounce (oz) bottles and graduated plastic cups were distributed for twice daily unsupervised weekend use. Coded 16-oz bottles were distributed for holidays and recesses. Subjects were required to maintain a diary of unsupervised rinse use. Subjects followed their usual oral hygiene regimen, with no dental treatment, scaling, or polishing prior to the rinse regimen.

All intraoral examinations were performed by the same examiner. Gingivitis was scored using the modified Loe and Silness Gingival Index which adds an additional score between the 1 and 2 of Loe and Silness, thus having two levels of ''Mild Inflammation,'' and eliminates the bleeding component from the original criteria for ''Moderate Inflammation.'' This index was later published by Lobene (Ref. 112) and is used in five of the eight ''definitive'' studies. Results (*see* Table 4 below) showed a continuous decline in adjusted mean gingivitis scores for each of three groups from baseline through 6 months.

TABLE 4.—RESULTS OF THE LAMSTER STUDY GROUP

Group	Baseline	1 month	3 months	6 months
Essential Oils	2.62	2.08	1.57	1.20
Vehicle Control	2.67	2.20	1.94	1.66
Water Control	2.66	2.32	1.93	1.67

Mean scores for the fixed combination of essential oils were statistically significantly less than controls at 3 and 6 months and 28 percent less than either control group mean score at 6 months. Control groups of this monitored, supervised, mostly young, dental school population continued to show a decrease in mean gingival index scores over time. No bleeding assessments were made.

A second study (Ref. 104) involved mostly dental students and staff of the same university, with the same inclusion criteria. Subjects were randomized into three groups, with 44 in the essential oils group (mean age 25 years), 38 in the vehicle control (a 26.9-percent hydroalcoholic vehicle containing all the ingredients in the test product except the essential oils) group (mean age 29 years), and 45 in the water control group (mean age 27 years). Upon entering the study, all subjects had a dental prophylaxis (defined as a scaling and rubber cup polishing), followed in 3 weeks by a baseline 1 examination. Two additional prophylaxes were done for each subject 4 to 7 days apart, followed in 3 to 4 days by a baseline 2 assessment. Prior to the first rinse, another (fourth) polishing was done. Subjects were randomly assigned to either the fixed combination of essential oils, a vehicle control, or a colored water control.

Supervision of rinsing and monitoring was the same as in the first study and gingivitis was scored as before. No bleeding assessment was done. Results (*see* Table 5 below) were recorded at 1, 3, and 6 months, with all assessments performed by one examiner. No intra-examiner variability testing is noted. Eighty-five subjects completed an additional 3 months of unsupervised rinsing. Most of the subjects who did not participate for the additional 3 months of the study were recently graduated dental students who were not available for the 9-month examination. The 6–month mean gingival index score for the essential oils was 10.4 percent less than the water control and 6.5 percent less than the vehicle control, but no statistically significant differences existed between groups for any interval.

TABLE 5.—MEAN GINGIVAL INDEX SCORES FROM THE GORDON STUDY

Group	Baseline 1	Baseline 2	1 month	3 months	6 months
Mean Gingival Index Score					
Essential Oils	1.60	1.39	1.54	1.27	1.31
Water	1.60	1.38	1.55	1.38	1.46
Vehicle	1.59	1.33	1.49	1.25	1.37

Mean gingival index scores for the 127 subjects who completed 6 months of the study were as follows: 1.23 for the essential oil group, 1.42 for the vehicle control group, and 1.57 for the water control group. Results for the 85 subjects who completed 9 months showed a statistically significant difference in mean gingival index scores, as follows: 1.12 for the essential oils, 1.43 for the vehicle control, and 1.52 for the water control.

The investigators stated that the lack of difference for gingivitis observed between groups for 6 months was probably due to improvement in gingival health resulting from four prophylaxes initially, followed by continuation of usual oral hygiene.

A third study involving 115 subjects in two study groups (essential oils and

5–percent hydroalcohol) was conducted at the University of Maryland using the same protocol (Ref. 105). Of the 115 subjects, 107 completed the study; 60 percent were male, 40 percent were female; 17 percent were smokers and 83 percent were nonsmokers. Each subject received a dental prophylaxis on the day the first rinse was given. Baseline gingival index scores were recorded prior to the prophylaxis and after 7 days of treatment. Fifty-four subjects (mean age 28.5 years) were in the essential oils group and 53 subjects (mean age 27.6 years) were in the 5–percent hydroalcohol control group. The analysis (*see* Table 6 below) was based on adjusted mean gingival index scores at 3 and 6 months.

TABLE 6.—ADJUSTED MEAN GINGIVAL INDEX SCORES FROM THE DEPAOLA STUDY

Group	Baseline 1	3 months	6 months
Essential Oils	2.288	1.522	0.918
5% hydroalcohol	2.200	1.576	1.385

Results included the distribution of gingival index scores in percentage at both baselines and at 6 months. No zero scores were recorded at baselines 1 and 2, but zero scores accounted for 38 percent of all scores in the essential oil group and 19 percent of all scores in the control group at 6 months.

The fourth study (Ref. 113), conducted at the University of Maryland, included a bleeding index (Ref. 114) in addition to the established inclusion criteria, assessments, and regimen of supervised rinsing twice a day on weekdays. This study compared the fixed combination of essential oils to 0.12 percent chlorhexidine gluconate and a control solution of flavored, colored 5 percent alcohol. There were 41 subjects in the essential oils group (mean age 29.2 years), 41 subjects in the chlorhexidine gluconate group (mean age 29.2 years), and 42 subjects in the control group (mean age 28.6 years). Following baseline examination, all subjects were given a dental prophylaxis. Assessments were made at 3 and 6 months. Two examiners were used, but only one examiner recorded gingivitis, plaque, and bleeding indices. Teeth used for a plaque collection at time of assessment were eliminated from statistical analysis for gingival, bleeding, and plaque indices. The specific teeth used were not cited in this report. Adjusted mean gingival scores (*see* Table 7 below) were presented for 3 and 6 months.

TABLE 7.—ADJUSTED MEAN GINGIVAL SCORES FROM THE OVERHOLSER STUDY

Group	Baseline	3 months	6 months
Essential Oils	2.234	1.328	0.748
Chlorhexedine Gluconate	2.281	1.032	0.810
5% Hydroalcohol Control	2.221	1.409	1.166

At 6 months, both active mouthrinses were statistically significantly different than the control in gingival index scores; the mean value of the essential oils score was 35.9 percent less than the mean value of the control score.

The distribution of gingival index scores at baseline and at 6 months for scores 0, 1, 2, and 3 were also presented in percentages. No zero scores were recorded at baseline. At 6 months, the percentage of gingival units with zero scores was 26 percent for control, 46 percent for the essential oils and 43 percent for chlorhexidine gluconate. Scores 1 and 3 were comparable for the three study groups but score 2 differed, decreasing from baseline to 6 months from 74 to 17 percent for the essential oils, 70 to 23 percent for chlorhexidine gluconate, and 74 to 34 percent for the control.

Bleeding index scores (*see* Table 8 below) declined for all groups and were not statistically significantly different at 6 months.

TABLE 8.—BLEEDING INDEX SCORES FROM THE OVERHOLSER STUDY

Group	Baseline	3 months	6 months
Essential Oils	.71	.40	.29
Chlorhexedine Gluconate	.72	.28	.25
5% Hydroalcohol Control	.66	.37	.33

Mankodi (Ref. 115) conducted a similar study using the Loe-Silness Gingival Index, thus adding a bleeding component. This study compared the combination of essential oils to the same formulation with the addition of mint flavor and a 5-percent water-alcohol control. Each subject was given a prophylaxis on the day rinsing began. There were 42 subjects in the essential oils group (mean age 31.1 years), 44 subjects in the essential oils plus mint group (mean age 30.6 years), and 38 subjects in the control group (mean age 33.1 years). The percentage difference between mean gingival index scores (*see* Table 9 below) at 6 months showed a score for the essential oils (0.90) that was 22.4 percent less than the control score (1.16).

TABLE 9.—MEAN GINGIVAL INDEX SCORES FROM THE MANKODI STUDY

Group	Baseline	3 months	6 months
Mean Gingival Index Score (adjusted for 3 and 6 months)			
Essential Oils	1.19	0.93	0.87
Essential Oils plus Mint	1.22	1.00	0.91
Control	1.23	1.10	1.18

A second study by Mankodi *et al.* (Ref. 116) compared the effects of the combination of essential oils, chlorhexidine gluconate, and a 5-percent water-alcohol control. There were 34 subjects (mean age 32 years) in the essential oils group, 36 subjects (mean age 31.4 years) in the chlorhexidine gluconate group, and 38 subjects (mean age 32.2 years) in the water-alcohol control group. The protocol was similar to the earlier studies with the exception of the use of the Russell Periodontal Index ''to further describe the study population,'' and the use of the Loe and Silness Gingival Index for assessment. The results (*see* Table 10 below) showed a statistically significant difference between the essential oil and control groups at 6 months, with the mean gingival index score for the essential oils group being 14.0 percent less than the mean score for the control group.

TABLE 10.—MEAN GINGIVAL INDEX SCORES FROM THE MANKODI STUDY

Group	Baseline	3 months	6 months
Mean Gingival Index Scores			
Essential Oils	1.31	1.22	1.04
Essential Oils Plus Mint	1.35	1.04	0.99
Control	1.27	1.18	1.21

A third study by Mankodi (Ref. 117) compared the effects of the combination of essential oils, the same combination plus flavor, and a 5–percent water-alcohol control. There were 48 subjects in the essential oils group (mean age 32 years), 43 subjects in the essential oils plus mint group (mean age 32 years), and 50 subjects in the water-alcohol control group (mean age 34 years). The protocol was similar to previous studies, but supervision on weekdays was limited to one of the two daily rinses, and this study used the Lobene modification of the Loe-Silness Gingival Index. Subjects received a prophylaxis following their baseline examination. Gingivitis was scored at baseline, 3 months, and 6 months. All intraoral examinations were performed by a single qualified dental examiner. Units of statistical analysis were the respective mean index scores determined for each subject. Gingival indices were analyzed by the analysis of variance, using baseline scores as the covariant. Results of gingival index scoring (*see* Table 11 below) are adjusted means for 3 and 6 months. Mean score percent reduction from control at 6 months for the combination of essential oils plus flavor was 10.8 percent and 10.2 percent for the combination without flavor. Both active groups are statistically significantly different at 6 months.

TABLE 11.—MEAN GINGIVAL INDEX SCORES FROM THE MANKODI STUDY

Group	Baseline	3 months	6 months
Essential Oils Plus Mint	2.16	1.68	1.66
Essential Oils	2.20	1.63	1.67
Control	2.19	1.82	1.86

An eighth 6-month controlled trial (Ref. 118) used the fixed combination of essential oils and a ''flavor variant'' control. The results showed the mean gingival scores significantly lower than the control group at 6 months.

These studies demonstrated that the fixed combination of essential oils has some effectiveness in preventing inflammation of the gingiva. The initial analyses relied solely on statistical hypothesis testing (the use of p values), which does not convey important quantitative information. However, a number of concerns (strength of the effect and its statistical significance, the generalizibility of the studies to the population which can most benefit, and the unit of analysis (subject versus site)) were resolved to make a valid determination as to the strength of antigingivitis efficacy for these ingredients.

Generalizibility of randomized, controlled trials to the population who will use the product is a concern. These studies use young populations, weighted with dental students, where supervision and timing of use is present. Much of the population that will benefit from an antigingivitis agent is middle-aged and older, having fully crowned

and restored teeth, and abutment teeth, which have been omitted from scoring in these trials. These teeth are among the ones most in need of combating gingivitis.

Because it is the individual who is at risk, it is important to know if each subject has changed. Use of mean gingival index scores for each individual subject is the correct way to calculate the mean score for each trial group at various intervals. However, analysis of each site infers that all sites provide independent observations. This assumes that 100 sites in one subject provide the same outcome information as one site in each of 100 subjects. Differences between subjects are greater than variations within subjects (Ref. 119). The principle noted is ''In investigations where experimental units on different levels are employed, use the highest level unit as computational unit'' (Ref. 120). All sites within one subject are not at equal risk for gingivitis. Inflammation tends to be more overt at interdental areas than at lingual or facial sites. To quantify the findings (*i.e.,* who and how many in the study groups are affected, and by how much) and to present the findings with appropriate indicators of measurement error or uncertainty (such as confidence intervals), further analyses were completed.

Data from pooled analyses of the eight 6-month studies were presented to the Subcommittee. Results showed that mean index values for men differed between the control and essential oils regimen and were similar to differences seen in women for gingival bleeding, gingival index, and plaque index. Differences in mean values between the control and active agent were presented for subjects aged 18 to 39 years and were similar to differences seen in subjects 40 years old and older. The percent of subjects who improved in bleeding, gingival index, and plaque scores from the initial exam to 6 months was greater in the essential oil group than the control group.

Pooled data from the eight studies were used to compute the odds ratio for reduction in gingival index score. The odds ratio was 4.21 with a 95-percent confidence interval (CI) of 2.79 to 6.36 to achieve a goal of 33 percent reduction in score. The bleeding score odds ratio for all studies where bleeding was assessed was 5.12 (CI 3.29 to 7.97). Again, the target goal was a 33-percent reduction in score. For the reported plaque index score reduction of 33 percent, the pooled (eight studies) odds ratio was calculated at 10.53 (CI 7.06 to 15.71).

The Subcommittee concludes that a combination containing eucalyptol (0.092 percent), menthol (0.042 percent), methyl salicylate (0.060 percent), and thymol (0.064 percent) in a hydroalcoholic vehicle containing 21.6 to 26.9 percent alcohol in a mouthrinse meets the requirements of FDA's policy regarding fixed combinations of OTC active ingredients with the same pharmacological action. The Subcommittee concludes that each of these ingredients contributes to the antibacterial activity of the combination, and that each is safe individually and in combination.

Based on the data submitted, the Subcommittee concludes that the combination of eucalyptol (0.092 percent), menthol (0.042 percent), methyl salicylate (0.060 percent), and thymol (0.064 percent) in a hydroalcoholic vehicle containing 21.6 to 26.9 percent alcohol in a mouthrinse is safe and effective as an OTC antigingivitis/antiplaque agent.

B. Category II Conditions

None.

C. Category III Conditions

The available data are insufficient to permit final classification at this time. Data to demonstrate safety and effectiveness as an antigingivitis/antiplaque agent will be required in accordance with the guidelines set forth above (*see* general guidelines on safety and effectiveness in section II.H of this document.)

1. Category III Single Active Ingredients

Aloe vera
Dicalcium phosphate dihydrate
Hydrogen peroxide
Sanguinaria extract
Sodium bicarbonate
Sodium lauryl sulfate
Zinc citrate

a. *Aloe vera*. The Subcommittee concludes that there are insufficient data to permit final classification of the safety and effectiveness of aloe vera as an OTC antigingivitis/antiplaque ingredient. Aloe vera (known in commerce as Curacao Aloe) is a brownish black, opaque mass with a fractured surface that is uneven, waxy, and somewhat resinous (Ref. 121). Aloe vera is obtained from the parenchyma tissue in the center of the leaf by mechanical or chemical means and is highly variable in its properties. The main constituents are polysaccharides, mainly glucomannans, anthraquinone glycosides, and glycoproteins. Other constituents may include sterols, saponins, and organic acids. Aloe vera is topically applied as an emollient, to aid in wound healing, and relieve burns (including sunburn), and is used for colonic irrigation. Extracts of aloe vera have been shown to enhance phagocytosis (ingestion by a cell of particulate material, such as microorganisms) in adult bronchial asthma. It is also used as an ingredient in many cosmetic preparations (Ref. 122). Aloe vera is produced by boiling Aloe juice down and pouring the viscous residue into empty spirit cases, in which it is allowed to solidify. Aloe vera possesses a nauseating and bitter taste and a disagreeable, penetrating odor. It is almost entirely soluble in 60 percent alcohol and contains not more than 30 percent of substances insoluble in water. Solutions of aloes gradually undergo change and, after a month, may no longer react normally and may lose the bitterness natural to aloes (Ref. 123).

i. *Safety*. The safety of aloe vera is difficult to discern from the data. However, there are studies in which the toxicity of components of aloe vera are discussed, *e.g.,* the component, acemannan (Ref. 124). Also, there is evidence that application of aloe vera to wounds will delay healing (Refs. 125 and 126). The Subcommittee concludes that the data are insufficient to permit final classification of the safety of aloe vera.

ii. *Effectiveness*. The Subcommittee concludes that there are insufficient data to permit final classification of the effectiveness of aloe vera as an OTC antigingivitis/antiplaque ingredient.

Aloe vera, a plant extract, has been claimed to have antiinflammatory and antiprostaglandin effects, as well as cathartic effects (Ref. 127). There are also claims that aloe vera extract is effective against several gram-positive and gram-negative organisms as well as *C. albicans*. However, the Subcommittee finds that the studies are conflicting and that the concentrations required appear to be 20 percent to 90 percent.

The enzyme blend of protease, lipase, and amylase is described as contributing to 3 percent of the formulation reviewed. There is only a general rationale for use in periodontal disease for debridement resulting in reduction of deposits of hard and soft excretions. However, no valid scientific evaluation of this proposed activity is apparent from the submitted data or from the literature (Ref. 128). In addition, no specific testing of the formulation has been presented or was located in the literature (Ref. 128). Therefore, the Subcommittee concludes that there are insufficient data to permit final classification of the effectiveness of aloe vera as an OTC antigingivitis/antiplaque ingredient.

b. *Dicalcium phosphate dihydrate*. Dicalcium phosphate dihydrate is one of several phosphate preparations that have been used as buffers, fillers, and abrasives in OTC dentifrices and as inactive ingredients in numerous drug products. The Subcommittee concludes that dicalcium phosphate dihydrate is safe when used as a buffer, filler, or abrasive in a dentifrice, but not generally recognized as effective for OTC use as an antigingivitis agent.

i. *Safety*. The safety of dicalcium phosphate dihydrate has been established on the basis of animal experiments and consumer use as a primary component of oral care products. It is included in the list of inactive ingredients in OTC anticaries formulations (45 FR 20666 at 20670), and is also approved by FDA as an optional food additive ingredient in the manufacture of flour (21 CFR 137.105 and 137.185). Dicalcium phosphate dihydrate has a reported oral LD_{50} value of greater than 10 g/kg for rats, and a dermal LD_{50} value of greater than 7 g/kg for rabbits. It is nonirritating or slightly irritating on rabbit skin and in eye irritation tests, respectively. Rodent oral limit tests, dermal irritation tests, and human irritation tests using various dentifrice formulations containing 5 percent to 88 percent dicalcium phosphate dihydrate were submitted (Ref. 129). These studies were carried out using toothpaste containing from 5 percent to 88 percent dicalcium phosphate dihydrate. The LD_{50} in rats is greater than 16 g/kg for a toothpaste containing 60:40 weight to volume (w/v) suspension of dicalcium phosphate dihydrate. Oral tissue irritation or sensitization potential of toothpaste containing dicalcium phosphate dihydrate was also evaluated in a series of studies (Ref. 129). The tests were carried out by having the subject brush 7 days, 5 times a day to provide an exaggerated test for oral tissue irritation. In no instances were any of the dentifrices containing dicalcium phosphate dihydrate either irritating or sensitizing under conditions of the test.

No reports were available regarding the toxicity of ingested dicalcium phosphate dihydrate in humans. It is estimated that the average adult might consume 2 to 3 g of phosphorous per day and, with an extreme diet containing maximum quantities of additives and naturally occurring phosphorous, could consume 6 to 7 g per day. Ingestion of an entire medium-size tube of toothpaste would increase the phosphorous consumption by several g, an amount unlikely to be significantly toxic. The saline cathartic effect of large doses of phosphate-containing materials would tend to limit their absorption to nontoxic levels. The Subcommittee concludes that, in general, dicalcium phosphate dihydrate can be regarded as safe.

ii. *Effectiveness*. Studies of the short-term use of dicalcium phosphate dihydrate-containing dentifrices in man have shown reduction of supragingival plaque to be greater than toothbrushing with water (Ref. 129). These studies do not implicate dicalcium phosphate dihydrate as an active ingredient but rather might be explained by the abrasive effect of dicalcium phosphate dihydrate in assisting plaque removal by toothbrushing. Gingivitis reduction is also seen in such experiments, but this could also be related to the abrasive effects of dicalcium phosphate dihydrate and removing plaque. The Subcommittee believes there is no evidence for chemical interference with plaque formation or plaque removal and no evidence of dicalcium phosphate dihydrate as an antigingivitis agent. The Subcommittee concludes that, based on the available data, it would be inappropriate to claim that the plaque reduction associated with the use of this abrasive qualifies it as an antigingivitis/antiplaque agent.

c. *Hydrogen peroxide*. The Subcommittee concludes that hydrogen peroxide is safe at concentrations of up to 3 percent, but there are insufficient data available to permit final classification of its effectiveness at 1.5 to 3 percent concentrations for long-term OTC use as an antigingivitis/antiplaque agent.

Hydrogen peroxide was isolated by Thenard in 1818 and has been of commercial interest since the mid-nineteenth century. Hydrogen peroxide has been a component of OTC drugs such as topical antiinfectants, canker sore treatments, and earwax softeners. A 3-percent solution of hydrogen peroxide has been widely used as a topical antiseptic agent for suppurative (producing pus) wounds, inflammation of the skin and mucous membranes, by dentists for irrigation during root-canal therapy, and as a mouthrinse for acute necrotizing ulcerative gingivitis. Decomposition of hydrogen peroxide releases large volumes of oxygen, approximately ten times the volume of the solution. A 30-percent solution has been used for bleaching nonvital pulpless teeth.

The Advisory Review Panel on OTC Oral Cavity Drug Products classified hydrogen peroxide as a Category I ingredient for short-term use in oral wound cleansing and debriding in concentrations from 1.5 to 3 percent in aqueous solution (47 FR 22760 at 22906, May 25, 1982). Ten percent carbamide peroxide in anhydrous glycerin, which releases 3 percent hydrogen peroxide, is also classified in Category I. Hydrogen peroxide is listed in the USP (Ref. 130).

i. Safety. The Subcommittee evaluated the toxicity and mutagenicity of hydrogen peroxide. The toxicity data suggested that 1.5 to 3 percent hydrogen peroxide in aqueous solution has a low toxicity. When ingested in large doses, hydrogen peroxide produces esophagitis and gastritis (Ref. 131). Few primary systemic toxic effects are expected at low concentrations because hydrogen peroxide decomposes in the oral cavity (Ref. 132) and bowel before absorption can occur.

The acute toxicity of hydrogen peroxide depends on the concentration tested, with more concentrated solutions being relatively more toxic than dilute solutions. In rats, concentrations of 0.25 percent to 0.5 percent hydrogen peroxide added to drinking water decreased growth and increased mortality within 6 weeks (Ref. 133). Decreased body weight was seen in Osborne-Mendel rats given 0.45 percent hydrogen peroxide in drinking water for 5 months, but this decreased body weight was regained within 2 weeks after replacing the hydrogen peroxide-containing drinking water with tap water (Ref. 134). The decreased body weight was possibly attributed to decreased liquid intake when hydrogen peroxide was provided in the drinking water. In case studies, fatal poisoning (Refs. 135 and 136) has been reported for ingestion of hydrogen peroxide at concentrations exceeding 3 percent or excessive ingestion of 3 percent hydrogen peroxide. Generally, ingestion of household peroxide (3 to 9 percent) causes no significant toxic effects (Refs. 137, 138, and 139).

The LD_{50} of hydrogen peroxide has been established by Ito *et al.* (Ref. 140) as 1,567 mg/kg body weight in rats dosed with a 5-percent solution. The low acute toxicity of hydrogen peroxide is confirmed by unpublished data indicating an LD_{50} of 5,000 mg/kg body weight for 6 percent hydrogen peroxide in rats (Ref. 141).

Teratogenic activity has not been demonstrated for hydrogen peroxide (Ref. 142). Hydrogen peroxide can be absorbed through the oral mucosa (Ref. 143) and epidermis (Ref. 144), but the exposure of the oral cavity to hydrogen peroxide is generally limited since it undergoes rapid decomposition. After 1 minute of brushing, less than 20 percent of the hydrogen peroxide introduced into the oral cavity can be recovered (Ref 145).

In the oral cavity, toxic effects of hydrogen peroxide vary from pulpal alterations (Ref. 146) to gingival lesions (Refs. 147 and 148) and oral irritation in rats (Ref. 149) under certain conditions. Adding a 1- to 1.5-percent solution to drinking water resulted in apparent enamel demineralization in rats over an 8-week period (Ref. 149). This effect on enamel was possibly due to the hydrogen-ion (pH) concentration of the solution used rather than true carious lesions. In addition, no enamel solubility was found from an in-vitro experiment using a 1.5-percent aqueous solution on human enamel (Ref. 141).

The Subcommittee's discussion of mutagenicity is not intended to be a complete review of the literature concerning the mutagenic nature of hydrogen peroxide, but is intended to point out the apparent mutagenic safety concerns associated with hydrogen peroxide. Any mutagenic role of hydrogen peroxide will be further discussed with sodium bicarbonate and hydrogen peroxide in combination.

Numerous reports indicate a mutagenic role for hydrogen peroxide (Refs. 150, 151, and 152). Reviews on the genotoxicity of hydrogen peroxide can be found in reports by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) (Refs. 153 and 154) and in an overview of hydrogen peroxide genotoxicity presented at the Subcommittee meeting on December 4, 1995 (Ref. 155).

Hydrogen peroxide can produce hydroxyl radicals which are reactive but short-lived (Refs. 155 and 156). In vitro superoxide and hydroxyl radicals caused chromatic exchanges in mammalian cells and preneoplastic changes (Refs. 153 and 154). Although hydroxyl radicals and singlet oxygen can damage DNA in vitro, the genotoxic potential of hydrogen peroxide depends on the proximity of unprotected DNA. In vitro genotoxicity tests enhance the opportunity for DNA damage and are conducted in cells with defective DNA repair systems. Genotoxic effects are not seen with hydrogen peroxide in the presence of protective enzyme systems that are normally present intracellularly, in the presence of iron chelating agents, and in the presence of hydroxyl radical scavengers.

The mechanism of mutagenesis through superoxide radical production was also suggested by MacRae et al. (Ref. 157). In contrast to most of the references available, Taylor et al. (Ref. 158) suggested that hydrogen peroxide itself and not hydroxyl radicals was responsible for DNA strand breaks in epithelial and fibroblast cultures. Most carefully controlled in vitro studies have shown that the participation of transition metal ions, such as iron or copper, is required for DNA damage to occur (Ref. 159).

In some bacterial mutagenesis studies, hydrogen peroxide was found to be a weak mutagenic agent (Refs. 160 through 167). Many strains are not sensitive to hydrogen peroxide and hydroxyl radicals and mutations are only seen in certain bacterial strains that are sensitive to oxidative damage (Ref. 168). The addition of an external enzymatic metabolic source resulted in abolition of the weak genotoxic effects seen in sensitive bacterial strains. These enzyme sources are normally present throughout the body, and the presence of detoxifying enzymes may explain the lack of genotoxicity seen in whole animals that have been administered hydrogen peroxide. In the oral cavity, salivary peroxidase serves as the initial line of defense against hydrogen peroxide (Ref. 169).

Additional studies were conducted to evaluate systemic effects of long-term administration of hydrogen peroxide, and the endpoint measured was sister chromatic exchange (SCE), a very sensitive assay for genotoxic damage. Hydrogen peroxide was administered to hamsters for 6 months at 70 mg/kg (Ref. 170) and to mice for 3 months (Ref. 171). In both studies, there was no increase in SCE formation following long term ingestion of hydrogen peroxide. A single administration of a carbamide peroxide-containing dentifrice to rats at 1,000 mg/kg daily for 5 days did not increase the incidence of SCE (Ref. 172). Woolverton also examined two commercial carbamide peroxide-containing dental products for micronucleus formation. After two exposures, these products did not increase the incidence of micronucleated erythrocytes (Ref. 173).

Similar results were seen in a micronucleus assay for chromosomal damage in mice that were given hydrogen peroxide intraperitoneally or in drinking water at 0.6 percent for 2 weeks (Refs. 174 and 175). The SCE and micronucleus studies consistently demonstrated a lack of genotoxicity following hydrogen peroxide ingestion or intraperitoneal injection.

Hydrogen peroxide was reported to promote carcinomas in rodents following intraperitoneal injections (Ref. 176) and through its addition to drinking water (Refs. 177, 178, and 179). Duodenal hyperplasia has been found in the rat model following the addition of 1.5 to 3 percent hydrogen peroxide to drinking water (Ref. 176). Ito *et al.* (Ref. 140) observed similar toxicity with higher doses of hydrogen peroxide. In mice with reduced catalase activity, hyperplastic and neoplastic duodenal nodules were found (Ref. 179). Ito's report of the carcinogenicity of hydrogen peroxide has been evaluated by FDA toxicologists who concluded that the results of the study did not provide sufficient evidence to designate hydrogen peroxide as a carcinogen (53 FR 53176, December 30, 1988). Similar conclusions were drawn by a panel of toxicologists who reviewed the potential carcinogenicity of hydrogen peroxide for the International Agency for Research on Cancer (IARC) (Refs. 180 and 181).

A long-term study was conducted in F344 rats in which hydrogen peroxide was administered in drinking water for 18 months at concentrations of up to 0.6 percent, the maximal tolerated dose in F344 rats (Ref. 182). All surviving animals were sacrificed at 24 months of age. Hydrogen peroxide ingestion in the 0.6-percent hydrogen peroxide group was 677 mg/kg/day for females and 433 mg/kg/day for males, with a total ingestion of 72.7 g hydrogen peroxide in females and 81.4 g hydrogen peroxide in males during the course of the study. There was no evidence of carcinogenicity at any organ site in this study following hydrogen peroxide ingestion.

In Syrian hamsters, applications of 3 percent and 30 percent hydrogen peroxide produced pathogenic changes associated with preneoplastic lesions. Preneoplastic lesions are reversible following cessation of exposure (Ref. 178). When combined with DMBA, a known carcinogen, hydrogen peroxide, at a concentration of 30 percent, appeared to augment the carcinogenic effects associated with DMBA (Ref. 183). No carcinogenicity was seen in this study resulting from hydrogen peroxide alone at concentrations of 3 or 30 percent.

Marshall et al. (Ref. 184) conducted two carcinogenesis studies of 16 weeks and 20 weeks in hamsters to compare the effects of similar dentifrices with and without the combination of hydrogen peroxide and sodium bicarbonate in the presence of DMBA. The authors reported that the results demonstrated that an oral product containing hydrogen peroxide and sodium bicarbonate was not carcinogenic and that the combination did not enhance the tumorigenicity of DMBA. In summary, these robust animal studies (Refs. 183 and 184) indicate that hydrogen peroxide does not increase the incidence of oral cavity tumors in combination with a known carcinogen.

Several studies challenge the carcinogenesis of hydrogen peroxide. Cell culture experiments rich in catalase show a marked decrease in the mutagenic effects of hydrogen peroxide (Refs. 185 and 186). Further, variations exist between species in their ability to control the destructive effects by the release of catalase and reduced glutathione (Ref. 187). The mutagenic potential of hydrogen peroxide as measured by production of hydroxyl radicals in the presence of Fe2+ has also been shown to be concentration dependent in a Chinese hamster cell line (Ref. 188). Additional mechanistic studies (Refs. 189 and 190) also suggested that the gel and paste phases of a toothpaste reduce the formation of free radicals. A generous supply of catalase in the oral cavity and studies demonstrating that hydrogen peroxide is rapidly degraded in the oral cavity indicate that hydrogen peroxide is unlikely to have a mutagenic potential at concentrations up to 3 percent (Ref. 191).

The ECETOC 1992 Joint Assessment of the toxic effects of hydrogen peroxide (Refs. 153 and 154) had the following conclusions: (1) Hydrogen peroxide concentrations of less than 1 percent do not appear to have gastrointestinal (GI) tumor-promoting potential; (2) chronic ingestion of 0.1 to 0.15 percent hydrogen peroxide causes an inflammatory response in gastroduodenal tissue of mice; (3) the mutagenicity of hydrogen peroxide in bacteria is a function of the genotype of the strain; (4) hydrogen peroxide has genotoxic potential only through the direct exposure of hydroxyl radicals on target DNA; (5) catalase reduces or abolishes the mutagenic response to hydrogen peroxide; (6) in vivo, many factors may contribute to the reduction of bioavailable hydrogen peroxide for systemic genotoxic action; (7) the possibility of genotoxic effect on cells that directly contact hydrogen peroxide at the site of application cannot be ruled out; and (8) no data are available to fully evaluate chronic toxicity and resulting carcinogenic potential of hydrogen peroxide.

The rate of decomposition of hydrogen peroxide in the oral cavity was determined in adults, children, and xerostomics. Hydrogen peroxide decomposition was so rapid that it was difficult to establish a rate of decomposition. In all cases, less than 27 percent of the hydrogen peroxide introduced into the oral cavity was present after 1 minute of brushing with dentifrices containing up to 3 percent hydrogen peroxide (Ref. 145). Most residual hydrogen peroxide would be expectorated with the dentifrice after brushing, leaving very little for ingestion. Based on clinical studies and adverse event reporting, the lack of irritation to soft tissues of the oral mucosa following use of hydrogen peroxide-containing dentifrices provides further evidence of the safety of long-term use of hydrogen peroxide-containing dental products.

Hydrogen peroxide presents safety concerns at concentrations above 3 percent because of the lack of controlled studies conducted with concentrations between 3 percent and 30 percent hydrogen peroxide. Available evidence indicates that acute toxic effects encountered with high concentrations of hydrogen peroxide (i.e., 30 percent) are rapidly repaired, leaving no deleterious effects. The discussion above mentions only some of the many published articles detailing the mutagenic potential of this ingredient. Despite some safety concerns, the gathering of appropriate clinical data outweighs the currently documented risks, which are inconclusive. While the experimental data suggest a mutagenic effect of hydrogen peroxide, the Subcommittee's review of current data indicates that, at concentrations of up to 3 percent in oral care products, the risk appears to be especially minimal and hydrogen peroxide is safe for its intended use.

ii. *Effectiveness*. Because of the preponderance of anaerobic and microaerophilic microorganisms associated with most forms of periodontal disease, the testing of oxygenating agents to inhibit or kill these microorganisms is understandable. The primary killing mechanism for hydrogen peroxide is through the release of oxygen. Unfortunately, the action is short-lived and inhibited by organic matter.

Hydrogen peroxide added to a mouthrinse has been shown to increase the release of hypothiocyanate into saliva. Hypothiocyanate has been reported to be a bacteriostatic agent against some microbial species (Refs. 192 and 193) through the activation of the lactoperoxidase system (Ref. 194). The addition of hydrogen peroxide to human whole saliva resulted in increased amounts of hypothiocyanate and this effect was concentration dependent (Ref. 195). This study also showed that the concentration of hydrogen peroxide was critical to obtain optimum bacteriocidal effect. Incubation time for inhibitory effects required several minutes, which may be a significant stumbling block in utilizing exogenous hydrogen peroxide through this mechanism of action. Another study of the lactoperoxidase/hypothiocyanate antimicrobial mechanism found that rinsing with a solution containing hydrogen peroxide can readily produce hypothiocyanate, although the amount was dependent on the volume and pH of the rinse and the concentration and pH of the hydrogen peroxide (Ref. 196).

In a 2-week, crossover study, Wennstrom and Lindhe (Ref. 197) found that a hydrogen peroxide-containing mouthrinse effectively prevented the colonization of several morphological groups of microorganisms, e.g., fusiforms, filaments, motile and curved rods, and spirochetes. These groups have been repeatedly associated with several forms of periodontal diseases. Plaque and gingivitis scores were also markedly reduced. The concentration of hydrogen peroxide released was not determined. In another short-term study, a 1.5-percent hydrogen peroxide rinse significantly reduced both plaque and gingivitis scores over the 7-day test period (Ref. 198). In a study using a rat model in which test animals on a high cariogenic diet were inoculated with plaqueforming microbial species, a 10-percent urea (carbamide) peroxide gel and 1 percent hydrogen peroxide solution significantly reduced the accumulation of plaque (Ref. 199). A 3-week study using 10 percent urea (carbamide) peroxide gel compared with a placebo showed a significant decrease in gingivitis but no comparable reduction in plaque scores (Ref. 200). The authors suggested that the oxygenating effects of the test solution produced an environment unsuitable for the microbial species responsible for the development of gingivitis. Similar results were found in another 3-week study using 10 percent urea peroxide gel (Ref. 201).

In contrast, a 3-week study comparing 1 percent hydrogen peroxide, 0.12 percent chlorhexidine, and a placebo rinse found little effect of the hydrogen peroxide on gingivitis scores and no demonstrable effects on plaque scores (Ref. 202). A 2-week study using a 1.5-percent hydrogen peroxide rinse compared to a placebo showed no benefit from the hydrogen peroxide either as a rinse or when delivered by an irrigation system (Ref. 203).

Testing of an 11-percent urea (carbamide) peroxide gel in a 3-month study (Ref. 204) and a 6-month study (Ref. 205) showed that plaque scores were significantly reduced when compared to conventional oral hygiene toothpaste controls. However, no effect on gingivitis could be determined in either study. In an 18-month study comparing a 1.5-percent hydrogen peroxide rinse with a fluoridated rinse

in conjunction with toothbrushing in subjects undergoing orthodontic treatment, a clear benefit was found for the hydrogen peroxide rinse group (Ref. 206). The rinse appeared to prevent the accumulation of plaque and the subsequent development of gingivitis. However, once plaque formed, the experimental rinse did not reduce the established plaque and gingivitis. In contrast, a 24-week study comparing a 1.5-percent hydrogen peroxide rinse with water rinses did not find a significant reduction in either plaque scores or in papillary bleeding scores (Ref. 207). A 2-year study comparing a 1.5-percent hydrogen peroxide rinse with a 0.1-percent chlorhexidine rinse, but without a placebo control, found a reduction in sulcus bleeding but not plaque scores for the hydrogen peroxide group (Ref. 208).

The Subcommittee concludes that there is a lack of well-controlled studies of sufficient length to draw firm conclusions regarding the effectiveness of hydrogen peroxide. The clinical data suggest that hydrogen peroxide may positively effect plaque and gingivitis scores, but the data are contradictory, lacking well-controlled clinical studies of adequate length. Further studies are needed to determine the value of this ingredient as an antiplaque agent. Optimizing the concentration, required exposure time, and best delivery vehicle would be major steps forward. The potential positive effect as an active ingredient is suggested by the current data. However, long-term efficacy is unknown.

d. *Sanguinaria extract*. The Subcommittee concludes that sanguinaria extract at 0.03 to 0.075 percent concentration is safe, but there are insufficient data available to permit final classification of its effectiveness in an oral rinse or dentifrice dosage form as an OTC antigingivitis/antiplaque active ingredient.

Sanguinaria extract is prepared by warm acidulated alcoholic extraction of the rhizome of *Sanguinaria canadensis* (more commonly known as blood root or puccoon), followed by precipitation with a metal salt. Six principal benzophenanthridine alkaloids are present in the extract with sanguinarine (50 percent) and chelerythrine (25 percent) being the major ones. Sanguinaria extract is a bright orange, free-flowing, amorphous powder that is hygroscopic and electrostatic. It is soluble at 25° C in methanol to 1 percent weight per weight (w/w), in chloroform to 0.75 percent w/w, in water or water buffered with one percent citric acid to 2 percent w/w. Sanguinaria extract exhibits a pH dependent lipophilicity and partitions to a significant extent into the lipid phase of a lipid/water mixture above pH 6.5. Sanguinaria extract has been described in several pharmacopeia (Refs. 209 and 210) and textbooks (Ref. 211). Uses include relief of spongy and red gums and in OTC cough syrups as an expectorant. Sanguinaria extract was introduced into homeopathic practice in 1837.

i. *Safety*. Safety studies addressing acute toxicity, irritation potential, sensitization potential, reproductive toxicity, birth defect potential, chronic organ toxicity, and carcinogenic potential were conducted in animals using sanguinaria extract and sanguinarine chloride.

The acute toxicity of sanguinaria extract was determined by oral gavage to Sprague-Dawley rats with doses from 500 to 3,000 mg/kg. In one study (Ref. 212), the oral LD_{50} of sanguinaria extract was 1,440 mg/kg. This suggests that sanguinaria extract is probably poorly absorbed orally. The lethal dose of sanguinaria extract in two Cynomolgus monkeys was above 50 mg/kg. The acute dermal LD_{50} in a limited study using 10 adult New Zealand rabbits was greater than 200 mg/kg body weight. Acute inhalation toxicity of sanguinaria extract (2.2 mg/liter) in 10 rats resulted in mortality in 3 of 5 males and no females. Gross pathology examination revealed no lesions or abnormalities. The LD_{50} from two studies of sanguinarine chloride determined by oral gavage in rats was 1,525 and 1,663 mg/kg. The intravenous LD_{50} in rats was 28.7 mg/kg, and the intraperitoneal LD_{50} in mice was 17.7 mg/kg.

Studies concerning the multidose subchronic toxicity of sanguinaria extract (Refs. 213, 214, and 215) and sanguinarine chloride (Refs. 216, 217, and 218) were conducted in rats and monkeys at doses ranging from 5 to 405 mg/kg for 2 to 13 weeks. In a 4-week oral gavage study in monkeys (Ref. 215), 100 mg/kg of sanguinaria extract was determined to be the appropriate high-dose for a subsequent 13-week toxicity study in monkeys. A 13-week gavage study in monkeys (Ref. 216) with 0 to 60 mg/kg showed no treatment-related toxicity except minor GI irritation of limited duration. The study suggested a NOAEL of 30 mg/kg per day once tolerance is achieved. A 13-week oral gavage study in rats (50 to 400 mg/kg per day) (Ref. 214) showed evidence of dose-related toxicity, principally involving GI irritation and body weight loss at all dosage levels. Mortality was observed at doses of 100 mg/kg per day and above, with a NOAEL of less than 50 mg/kg per day. Administration in the diet appears to protect against GI irritation. A 4-week dietary toxicity study in rats (5 to 405 mg/kg per day) (Ref. 213) showed a group mean body weight loss at 405 mg/kg. Based on these studies, evidence of minor treatment-related toxicity associated with sanguinaria extract and sanguinarine chloride is limited to GI irritation.

Pharmacokinetic studies assessing metabolism, disposition, distribution, and elimination of sanguinaria extract and sanguinarine chloride were conducted in rats and mice (Refs. 219, 220, and 221). The metabolism of sanguinaria extract was tested in vitro in rat and rabbit liver homogenates and in vivo in 10 human subjects for at least 6 months (Ref. 219). Results indicated that no benz[c]acridine (50 parts per billion (ppb) detection limit) was formed in the rat or rabbit liver homogenates. Neither benz[c]acridine (1 ppb detection limit) nor sanguinarine chloride (25 ppb detection limit) was found in the urine of the human subjects.

Studies evaluating the biological disposition of radiolabeled sanguinarine chloride in rats (Ref. 220) and mice (Ref. 221) suggested low absorption, with excretion of over 50 percent (mice) and 88 percent (rats) of the total dose in feces. Less than 1.0 percent (rats) and 0.9 percent (mice) was excreted in the urine.

Analysis of rat tissues collected 96 hours following oral administration of 5 mg/kg indicated a total recovery of approximately 6.1 percent of the administered radioactivity. Excretion via urine, feces, and expired air accounted for 95.1 percent of the administered dose in the 96-hour post-administration period. Blood levels in the rat achieved less than 1.5 percent of the net dose administered orally, peaking around 8 hours and declining to near 1 hour levels by 96 hours.

Expired air accounted for an average of 18.3 percent (mice) and 6.0 percent (rats) of the dose administered. The nature of the blood radioactive residues and excreted ^{14}C-carbon was not determined. An overall mean recovery in mice of 97.89 percent of the ^{14}C-carbon during the 96 hours following oral administration of sanguinarine chloride labeled at one and/or both methylene-dioxy groups suggests that a substantial portion of the radiolabeled test product may be transformed into nonlabeled benzophenanthridine metabolites. These results suggested that sanguinarine chloride is satisfactorily recovered after oral or intravenous administration.

A cardiovascular study in dogs treated intravenously with sanguinarine

chloride (0.075 mg/kg) demonstrated no treatment-related effect on heart function or cardiovascular health (Ref. 222) at a dose 30 times the maximum daily absorbed dose expected from brushing and rinsing.

Sanguinaria extract was tested in a fertility/reproduction study in rats (Ref. 223), in developmental toxicity studies in rats and rabbits (5 to 400 mg/kg per day) (Refs. 224, 225, and 226), and in a perinatal/postnatal study in rats (5 to 60 mg/kg per day) (Ref. 227). The NOAEL level of sanguinaria extract was 25 mg/kg per day for development toxicity in rabbits, and 15 mg/kg per day for maternal toxicity. Sanguinaria extract had no effect on fertility, reproduction, or fetal and neonatal development in rats and rabbits at doses below those resulting in general toxicity in the adult animals.

Mutagenicity studies were conducted with both sanguinaria extract and sanguinarine chloride with in vitro methods using microorganisms and mammalian cells in culture and in vivo in mice. Weak positive responses were elicited only in the bacterial assay using Salmonella typhimurium (Ames assay) in the presence of metabolic activation (Ref. 228). Studies of sanguinaria extract were negative in the bacterial assay with Escherichia coli (Ref. 229), in an unscheduled DNA synthesis assay in rat primary hepatocytes (Ref. 230), and in a micronucleus cytogenetic assay in mice (Ref. 231). An Ames test for metabolites of sanguinaria extract in rat urine using *S. typhimurium* was negative. Studies of sanguinaria chloride were negative in other Ames assays with *S. typhimurium* (Ref. 232), and *Saccharomyces cerevisiae* (Ref. 233) with and without metabolic activation. Two mammalian cell assays (Ref. 234) with sanguinarine chloride, including a Chinese hamster ovary (CHO)-hypoxanthine-guanine phosphoribosyltransferase (HGPRT) forward gene mutation assay and unscheduled DNA synthesis assay in rat primary hepatocytes (Ref. 235) provided results that were equivocal or uninterpretable. Neither study, however, gave a positive mutagenic response. The CHO assay is historically difficult to conduct and interpret.

Long-term (90 to 98 weeks) carcinogenicity studies (Ref. 236) by gavage at dosages of 0 to 60 mg/kg per day sanguinaria extract in rats did not produce treatment-related preneoplastic or neoplastic lesions to suggest a carcinogenic effect. Dosage at 40 mg/kg per day did not produce toxicity and is considered the NOAEL dosage. A lifetime diet carcinogenicity study of sanguinaria extract was evaluated in rats (8 to 200 mg/kg per day) (Ref. 237). No test related hematological, biochemical, or urological changes were observed at any dosage level. No test article related macro- or microscopic pathology changes were observed. A 200 mg/kg per day dosage level can be considered the NOAEL level.

Two controlled 13-week subchronic studies done in monkeys and dogs (Ref. 238) examining ocular toxicity provided no evidence that sanguinaria extract or sanguinarine chloride affected intraocular pressure or produced any other ophthalmologic changes.

Human exposure to sanguinarine with twice daily use of toothpaste and oral rinse has been estimated to be 0.056 mg/kg per day (Ref. 238). Comparison of doses tested in animal studies with human doses expected from use of toothpaste or oral rinse appears to support the use of sanguinaria extract at a significantly higher concentration than contained in currently marketed products.

Ten animal safety studies conducted between 1982 and 1984 were submitted for dentifrice formulas containing 300 to 2,000 μg/mL of sanguinaria extract. None of the studies tested the currently marketed toothpaste formula containing 750 μg/mL of sanguinaria extract. Acute oral toxicity was greater than 20 g/kg in rats for a toothpaste formula containing 300 μg/mL of sanguinaria extract, and 5 g/kg in rats for a formula containing 500 μg/mL of sanguinaria extract (Refs. 239, 240, and 241). Primary skin and eye irritation studies carried out in rabbits (Refs. 242 and 243) demonstrated mild irritation reaction when a toothpaste formula containing less than 750 μg/mL was tested. Mild mucosal irritation was observed when a toothpaste formula containing 300 μg/mL of sanguinaria extract was tested in cheek pouches of hamsters (Refs. 244 through 248).

Two clinical studies (Refs. 249 and 250) demonstrated only mild mucosal irritation in test subjects. No differences were noted in the severity of lesions between the test and control groups.

Eleven clinical studies of animal safety conducted between 1983 and 1987 (Ref. 251) were submitted. Because modification of the oral rinse formulation from pH 3.2 to pH 4.5 began in 1989, none of these studies provided animal safety data on the currently marketed oral rinse (pH 4.5).

Based on data on the oral rinse formula containing 450 to 1,000 μg/mL sanguinaria extract at a pH of 3.2, no mucosal irritation was noted in the hamster cheek pouch (Refs. 252 and 253) or albino guinea pig studies (Ref. 254). No signs of toxicity or pharmacological effects were observed in test animals when a rinse formula of 450 μg/mL sanguinaria extract at pH 3.2 was tested (Ref. 255).

Four human studies conducted between 1982 and 1985 evaluated the irritation and sensitization potential of dentifrice formulas containing sanguinaria extract using a repeated insult patch test design involving a 2-percent aqueous slurry (Refs. 256 through 259). These studies demonstrated no induction of irritation or allergic contact dermatitis. An exaggerated use study (Ref. 260) using an earlier formula (300 μg/g sanguinaria extract) demonstrated no irritation or sensitization in soft oral cavity tissues. Two 6-month studies on a toothpaste containing sanguinaria and sodium monofluorophosphate (Refs. 261 and 262) showed no adverse effects on oral hard or soft tissues. Soft tissue examinations included inspection of the lips, tongue, hard and soft palate, gingiva, mucobuccal fold areas, inner surface of the cheeks, and sublingual areas. Although testing of the microbial flora was inconclusive in one study (Ref. 261), sanguinaria did not promote overgrowth through the development of resistant microbial strains.

A 6-month, double-blind, randomized study using a dentifrice containing 0.075 percent sanguinaria extract (Ref. 263) showed no significant oral irritation or adverse reactions. A 1-week exaggerated use study showed that 18 of the 28 subjects experienced mucosal sloughing (Ref. 264).

Although nine human safety studies were presented, only one study (Ref. 265) tested the currently marketed oral rinse containing 300 μg/mL of sanguinaria extract at pH 4.5. However, this study tested the efficacy of the formula and was not designed to test the safety of the oral rinse. Three of the remaining eight studies showed that repeated application of the earlier oral rinse formula at pH 3.2 under a semiocclusive patch test did not induce clinically significant irritation or evidence of induced contact dermatitis in humans (Refs. 266, 267, and 268). This earlier rinse formula gave no evidence of localized or generalized clinical manifestations in test subjects in two of the 7-day exaggerated use studies (Refs. 269 and 270). The Subcommittee concludes that sanguinaria extract at 0.03 to 0.075 percent concentration in an oral rinse or dentifrice dosage form is safe.

ii. *Effectiveness*. The Subcommittee reviewed controlled clinical studies ranging from 1 week to 6 months in duration. Three short-term studies (two 1 week and one 1 month) had equivocal results between the active and placebo toothpaste preparations. Of the three

studies that tested the currently marketed toothpaste containing 750 µg/g of sanguinaria extract, only one 6-month, double-blind study (Ref. 271) demonstrated a significant decrease in plaque at 3 months. Results from this study also showed that gingival index scores in the active group were significantly lower than the placebo group at 28 weeks. The other two studies were short-term studies of 1 and 4 weeks (Refs. 272 and 273) in which no differences were detected between the active and placebo groups. A 10-week study (Ref. 274) showed that the toothpaste formulation containing 300 µg/g of sanguinaria extract reduced plaque and gingival bleeding, but the zinc chloride in the formulation diminished the plaque-reducing effect. It was not clearly documented whether zinc chloride affects the effectiveness of the currently marketed toothpaste. Based on the short-term clinical studies, the effectiveness of the toothpaste containing 750 µg/g sanguinaria extract in plaque and gingivitis reduction cannot be determined. The effect of zinc chloride on the effectiveness of the toothpaste also needs further study.

Five studies used a toothpaste formula containing 750 µg/g sanguinaria extract and 0.8 percent sodium monofluorophosphate (Refs. 263, 264, 273, 275, and 276). Equivocal results were noted in two 6-month studies (Refs. 263 and 276) and in a 1-week study (Ref. 264). One toothbrushing study (Ref. 273) compared the effect of eight toothpaste formulations on plaque and gingivitis in school children. Because the study design concerning the control product and subject selection was inadequate, this study did not support effectiveness. One-way analysis of variance (ANOVA) showed that the differences between groups were not statistically significant. In addition, no significant differences in plaque or gingivitis reduction were noted between groups using a fluoride toothpaste containing zinc chloride plus sanguinaria extract and a dentifrice containing zinc chloride without sanguinaria extract.

A 1-week, exaggerated use effectiveness study (Ref. 275) tested three regimens of the toothpaste and oral rinse on plaque reduction. The study design and protocol employed did not allow accurate testing of the effectiveness of the toothpaste. Based on all of the data submitted, none of the studies provided evidence of effectiveness.

The Subcommittee evaluated 26 additional controlled clinical studies (Ref. 277). Seven of the 26 studies (Refs. 265 and 278 through 283) provided equivocal results. The remaining 19 studies (ranging from 1 to 8 weeks), conducted for various reasons, evaluated proper dosage, clinical study designs, optimal plaque and gingival indices to be employed, product safety, effectiveness of the regimen (toothpaste and oral rinse combination use), and the role of zinc chloride in plaque reduction.

Among the 19 studies, 9 tested the effectiveness of an oral rinse with a final pH of 4.5. Some short-term clinical trials, employing the 7-day exaggerated use study design, demonstrated statistically significant differences between an earlier rinse product (pH 3.2) and the placebo control in plaque reduction only. However, the only two long-term, 6-month studies testing the effectiveness of this earlier rinse product (pH 3.2) did not demonstrate any effectiveness in plaque or gingivitis reduction when compared to a placebo. The 7-day exaggerated use study design was validated as a screening test for formulation development (Ref. 284). In addition, studies investigating the role of zinc chloride in the effectiveness of the oral rinse provided confusing and controversial results. Two 1-week studies (Refs. 285 and 286) demonstrated that no significant difference in plaque reduction was observed between a sanguinaria extract and zinc chloride rinse and a rinse without sanguinaria extract. The effect of zinc chloride alone was only mildly less than that obtained with the combination of sanguinaria extract and zinc chloride. However, a 2-week, experimental gingivitis, crossover study (Ref. 287) demonstrated that the oral rinse with sanguinaria extract and zinc chloride performed significantly better than the placebo in plaque reduction. The effect on gingivitis was equivocal.

One study trial (Ref. 288) evaluated the effect of the oral rinse on viable microorganisms after a single 60-second rinse. The rinse exhibited a selective effect on anaerobic organisms without adversely affecting aerobes or alpha-hemolytic streptococci. No long-term studies were available.

While some data exist on the short-term effectiveness of the sanguinaria extract oral rinse or dentifrice, the Subcommittee evaluated selected studies that supported the effectiveness of the oral rinse used in combination with one of the sanguinaria toothpaste products. Five short-term (1 to 9 weeks) studies (Refs. 265 and 289 through 292) demonstrated reductions in plaque or gingivitis. Four 6-month studies also produced significant differences for the active regimen compared to placebo (Refs. 293 through 296). However, these nine studies varied substantially in design and formulation of the test dentifrice and oral rinse combinations. In studies prior to 1984, low dose toothpaste (300 µg/mL sanguinaria extract) and pH 3.2 oral rinse were used, whereas studies conducted since 1988 have included the 750 µg/g sanguinaria extract toothpaste and a pH 4.5 oral rinse. Even if effectiveness were demonstrated for the combined regimen, the contribution of sanguinaria extract alone is not clear.

The in vitro efficacy of the individual active components was also investigated. In vitro MICs of sanguinaria chloride and sanguinaria extract were tested against 176 clinical isolates and 43 reference strains of oral bacteria (Ref. 297). MIC's for sanguinaria chloride ranged from 16 to 32 µg/mL for all but 7 reference isolates. MICs for sanguinaria extract ranged from 16 to 24 µg/mL for all strains except *Wolinella succinogenes* and one strain of *Wolinella curva*. For fresh isolates, MIC's for sanguinaria chloride and sanguinaria extract ranged from 16 to 32 µg/mL. Laboratory tests were also conducted on sanguinaria and fluoride-containing toothpaste to evaluate the bioequivalence of the product to positive controls. Tests included bioavailability, rat caries fluoride stability (Ref. 298), remineralization/demineralization, and in vivo bovine enamel fluoride uptake (Ref. 299). These tests are consistent with the required biological testing procedures for fluoride dentifrices (October 6, 1995, 60 FR 52474 at 52510). Results obtained from these studies indicated that the sanguinaria/fluoride toothpaste formula was biologically equivalent to the clinically-tested control in promoting remineralization, promoting fluoride uptake into artificial enamel lesions, reducing the effects of acid challenge on enamel, and reducing caries in the rat caries model. Sanguinaria extract and zinc chloride were also shown not to interfere with fluoride bioavailability uptake profiles with decalcified enamel qualitatively comparable to profiles obtained from sound enamel.

The Subcommittee concludes that, although mild staining and oral irritation may occur, sanguinaria extract at 0.03 to 0.075 percent concentration is safe. However, given the wide variations in study designs, test product concentrations and formulations, placebo controls, and statistical analyses, conclusions cannot be drawn regarding the effectiveness of sanguinaria extract as an OTC antigingivitis/antiplaque agent.

e. *Sodium bicarbonate*. The Subcommittee concludes that sodium

bicarbonate is safe, but appears to have relatively poor efficacy as an OTC antigingivitis/antiplaque agent, requiring high dosages and extended exposure time to have a reasonable chance at affecting the oral flora and clinical parameters.

Sodium bicarbonate has been used as an antacid as well as advocated as an ingredient in both toothpastes and mouthrinses. It has been generally regarded as a bactericidal agent that generates a hypertonic (causing water to flow out of the cell) environment, leading to disruption of the fluid equilibrium of the cell and dehydration, plasmolysis (cell shrinkage due to loss of water by osmosis), and eventual cell death.

i. *Safety*. Sodium bicarbonate is GRAS for use in foods (21 CFR 184.1736). Sodium bicarbonate is listed as an OTC antacid up to a maximum daily dose of 200 milliequivalent (mEq) bicarbonate ion (21 CFR 331.11(k)(1)). The usual dose is 1 to 5 g, providing up to 60 mEq. In OTC mouthrinse applications, sodium bicarbonate has been determined to be safe and effective for use as a debriding ingredient (47 FR 22712 at 22907, May 25, 1982). Ingestion of large amounts of sodium bicarbonate causes several blood chemistry changes, including increased sodium levels, resulting in toxic effects that produce hypernatremia (excessive amount of sodium in the blood) (Refs. 300, 301, and 302). The LD_{50} is 7.57 to 8.9 g/kg body weight for the rat.

Sodium bicarbonate does not appear to be teratogenic or mutagenic using conventional testing, with no discernable effects on fetal survival in several species. It does not produce photosensitization, acute ocular irritation, or skin irritation by standard methods.

ii. *Effectiveness*. Few studies examine the effectiveness of sodium bicarbonate as a single active ingredient. Sodium bicarbonate has been found to be bactericidal to several oral microorganisms (Ref. 303). The authors suggest that the killing effect might be more than an osmotic imbalance created within the cells. This study showed several disturbing aspects about the effectiveness of this ingredient. For killing to be effective, relatively long periods of exposure were required, ranging from several minutes to hours. While a comparison to other antimicrobial agents is not intended as a criteria for effectiveness, sodium bicarbonate had a 10-fold poorer MIC range compared to sodium fluoride and a 1,000-fold poorer MIC range compared to sodium lauryl sulfate. In a study examining the effects of sodium bicarbonate on *S. mutans*, osmotic disruption occurred through salt concentration dependent cell lysis (Ref. 304).

In a 20-day experiment on rats, sodium bicarbonate applications were ineffective at reducing plaque accumulations (Ref. 305). In a 6-week study comparing the effects of a toothpaste containing sodium bicarbonate with a standard fluoride toothpaste, no increase in effectiveness was observed (Ref. 306). In a similar 8-week study, no difference was observed in either plaque or gingivitis scores between the control and sodium bicarbonate test toothpaste (Ref. 307).

The Subcommittee concludes that sodium bicarbonate is safe, but there are insufficient data available to determine its effectiveness as an OTC antigingivitis/antiplaque agent.

f. *Sodium lauryl sulfate*. The Subcommittee concludes that sodium lauryl sulfate is safe at concentrations of 0.1 to 5 percent, but there is insufficient evidence to support its effectiveness as an antigingivitis/antiplaque active ingredient. The Subcommittee notes, however, that sodium lauryl sulfate is a safe and effective foaming ingredient in toothpaste.

Sodium lauryl sulfate is a synthetic detergent that acts as an anionic surfactant to lower surface tension. Sodium lauryl sulfate is available commercially as a viscous liquid, paste, or powder. It may contain small amounts of other sodium alkyl sulfates, although it consists mostly of sodium lauryl sulfate with a molecular weight of 288.4 and the formula $CH_3(CH_2)_{10}CH_2OSO_3Na$. It is soluble in water and alcohols. It binds to positively charged tooth surfaces and positively charged side groups of proteins. Protein binding may lead to denaturation (loss of biological activity) through conformational changes in the molecule. It is stable in alkaline solutions and will hydrolyze (split into fragments by addition of water) at room temperature below a pH of 5 (Ref. 308).

Sodium lauryl sulfate is used in cosmetics such as shampoos, deodorants, facial makeup, shaving preparations, and bath products, and in various oral care products. It is approved as a multipurpose food additive (21 CFR 172.822). Its ubiquity in personal care products can be estimated by a 1981 FDA Cosmetic Product Formulation List that shows it as an ingredient in 703 products (Ref. 308). In oral care products, sodium lauryl sulfate is used as a foaming agent and is frequently combined with other ingredients. It is found in mouthrinses and dentifrices, usually in concentrations of 5 percent or less (Refs. 308 and 309). In most mouthrinses, it is found in concentrations of less than 1 percent. In skin care products, concentrations of sodium lauryl sulfate may range up to 50 percent. In the last two decades, sodium lauryl sulfate has replaced most other surfactants previously used for oral care drug products. It is estimated that 4 to 5 million pounds of sodium lauryl sulfate are used annually in the United States for oral health care products alone (Ref. 309).

The estimated daily intake of sodium lauryl sulfate of about 1 to 10 mg originates, in part, from personal products (including oral hygiene products), foods, and drinking water. Personal products account for about one-half or less of this intake (Ref. 310).

i. *Safety*. Extensive safety data, both in animals and humans, show that sodium lauryl sulfate has a very low level of toxicity at doses used in oral health care products, is rapidly metabolized through the liver, and has no genotoxic or teratogenic effects (Ref. 311).

1. *Absorption and excretion*. Sodium lauryl sulfate is poorly absorbed through the epithelial lining of the skin and mucosal surfaces. Aqueous radio-labeled sodium lauryl sulfate was applied to guinea pig skin in vivo by rubbing for 10 minutes, followed by washing and application of a nonocclusive dressing for 24 hours (Ref. 308). Most of the radioactivity was recovered on the skin at the experimental site, in the washing fluid, and in the dressing. Radioactivity of 0.1 percent was recovered from exhaled air and urine. No radioactivity was found in the internal organs, feces, or carcass. The studies concluded that the presence of a strong anionic terminal group impaired sodium lauryl sulfate penetration through the skin.

Rat skin was exposed for 15 minutes to radio-labeled (25 millimolar (mM)) sodium lauryl sulfate. Expired carbon dioxide, urine, feces, and skin were monitored for 24 hours. Autoradiography showed heavy concentrations of sodium lauryl sulfate on the skin surface and in the hair follicles. Quantifiable levels of sodium lauryl sulfate were also recovered in the urine (Ref. 308).

If linear alkyl sulfates, including sodium lauryl sulfate, are deposited on the skin after a wash and rinse application, only a small amount actually penetrates the skin (Refs. 312 and 313). Sodium lauryl sulfate is rapidly absorbed through the intestine of mammals, rapidly metabolized through the liver, and is excreted in the

urine. Sodium lauryl sulfate is oxidized to carboxylic acid with butyric acid-4-sulfate as the major metabolite (Ref. 314).

2. *Acute toxicity*. Sodium lauryl sulfate has an LD_{50} in rats ranging from 0.9 to 1.6 g/kg with a mean of around 1.3 g/kg (Refs. 315 and 316). Studies (Ref. 308) indicated that sodium lauryl sulfate is slightly toxic. Signs of toxicity included diuresis, diarrhea, lacrimation, salivation, tremors, convulsions, sedation, anaesthesia, and death.

Intraperitoneal administration of sodium lauryl sulfate (25 or 50 mg/kg body weight per day for 3 days) decreased the level of some cytochrome P450 species (Ref. 317), stimulated haem-oxygenase activity (Ref. 318), and affected serum lipids (Ref. 317). The concentrations of sodium lauryl sulfate and the routes of administration in these studies were specifically designed to induce toxic effects, including death, and have little in common with human exposure to this ingredient with normal use of mouthrinses and dentifrices.

3. *Chronic toxicity studies*. Rats fed a diet containing up to 2.25 percent sodium lauryl sulfate for 13 weeks demonstrated enlarged liver cells and increased liver weight, as well as elevated levels of alkaline phosphatase and glutamic pyruvic transaminase. These changes were considered to represent accommodations to the increased work load required for the metabolism of sodium lauryl sulfate. Other changes noted included nonspecific enlargement of the kidneys, increased water consumption, and enlarged intestinal lymphatics. The sodium lauryl sulfate level below which no changes could be detected was 0.14 percent of the dietary intake, or 116 mg/kg body weight (Ref. 319). Another study found the ''no change'' level to be 0.1 percent (Ref. 316).

In a 16-week feeding study in rats, daily doses of different percents of sodium lauryl sulfate in the diet had different results: 8 percent resulted in death, 4 percent in significant growth retardation, and 2 percent in some growth retardation that was not statistically significant (Ref. 320). In a 1-year study in dogs, a 2-percent dietary intake of sodium lauryl sulfate caused some weight loss. The ''no change'' level was 1 percent (Ref. 308).

The toxicology of alkyl sulfates has been extensively reviewed (Refs. 321 and 322). The Subcommittee notes several hypothetical examples (Ref. 313) that place the above findings in the context of human subject users. In the unlikely event of a 20-kg child ingesting 10 mL of a mouthrinse containing 0.3 percent sodium lauryl sulfate daily, over a 13-week period, the daily dose ingested would be 1.5 mg/kg body weight. Based on a ''no change'' level of 116 mg/kg in the rat feeding study, the safety factor is 77-fold (Ref. 319). The safety factor in a 50-kg adult ingesting 1 mL of the mouthwash daily would be over 1,900. Based on the 1-year study in dogs (Ref. 308), the safety factors for the child and adult would be greater than 500 and 13,000, respectively.

4. *Reproduction toxicity*. Teratogenic studies in rats (Refs. 323 through 326) revealed no evidence of teratogenicity. Some embryotoxicity was noted at high doses that were severely toxic to the dams.

5. *Mutagenic potential*. Neither in vivo (Refs. 327 and 328) nor in vitro (Refs. 329 and 330) assays resulted in any increase in chromosome aberrations. There is no evidence that sodium lauryl sulfate incorporated in oral health care products is a teratogenic or mutagenic risk in humans.

6. *Skin irritation*. At concentrations of 2, 10, and 20 percent, sodium lauryl sulfate produces a Draize skin irritancy test score compatible with that of a primary skin irritant (Ref. 308). The 1 to 6 percent concentrations of sodium lauryl sulfate applied to human skin under an occlusive patch for 21 days were irritating to the skin. However, no irritancy potential could be detected in the absence of the occlusive patch (Ref. 331). Therefore, open application of sodium lauryl sulfate produces little, if any, irritation at these concentrations.

7. *Ocular irritation*. The 10 percent sodium lauryl sulfate applied to the rabbit eye caused corneal damage if washing was delayed or withheld. A 1-percent sodium lauryl sulfate application caused little irritation and no corneal damage (Refs. 309, 321, and 322).

8. *Oral irritation potential*. Sodium lauryl sulfate solutions in concentrations of 0.1 to 1 percent in 12 percent ethanol were swabbed for 30 seconds 4 times daily for 4 days on the oral mucosa of rats. Only mild cheilitis (inflammation of the lips) and sloughing were observed (Ref. 332). A single application of 0.2 percent sodium lauryl sulfate to the oral mucosa of rats did not produce any detectable changes, whereas increased cellularity was observed with a 2-percent application in half of the animals. After 3 weekly applications, the cellular reaction decreased (Ref. 333).

The Subcommittee concludes that, based upon the results of the extensive toxicity tests (only some of which are referenced above), sodium lauryl sulfate does not constitute a risk to consumers in the concentrations found in oral health care products. The widespread use of sodium lauryl sulfate in numerous oral health care products, as well as in foods and other personal products, without any reported side effects attributable to normal use, further supports the safety of this ingredient.

ii. *Effectiveness*. The Subcommittee concludes that there are insufficient data available to permit final classification of the effectiveness of sodium lauryl sulfate as an antigingivitis/antiplaque agent.

Sodium lauryl sulfate is used in oral health care products because of certain desirable properties, which include: (1) Decreasing surface tension (Refs. 334 and 335), (2) affinity for enamel surfaces, leading to masking of receptor sites for bacterial proteins (Ref. 336), (3) emulsification of food and bacterial components (Refs. 334 and 337), (4) inhibition of selective enzymes that help form dental plaque (Refs. 337, 338, and 339), (5) affinity for bacterial proteins and ability to denature them (Ref. 337), (6) disruption of cell membranes (Ref. 340), (7) inhibition of plaque formation through decreased surface tension and competition with negatively charged bacterial cells for binding sites on the tooth surface (Ref. 341), and (8) optimization of antibacterial properties of certain zinc salts (Ref. 340).

These properties of sodium lauryl sulfate contribute to its usefulness to loosen and remove food particles (Refs. 342 through 349). Some of these properties also allow sodium lauryl sulfate to inhibit the formation of dental plaque (Ref. 350), exert a mild antibacterial effect (Ref. 351), and provide consumers with the feeling that tooth surfaces are smooth and clean and their breath is fresher (Ref. 352).

In examining the results of clinical trials involving sodium lauryl sulfate, the types of products containing this ingredient and the characteristics that make it desirable for a particular product should be considered. Because of differences in formulations and the presence of other ingredients, it may be difficult to determine to what extent sodium lauryl sulfate contributes to some of the beneficial effects claimed for marketed products. For example, a major objective for mouthrinse users is to reduce oral malodor. However, it is difficult to compare the effect of rinses containing sodium lauryl sulfate to those that do not, since flavoring agents are obvious confounding factors (Refs. 352 through 357). The most common oral health care products that contain sodium lauryl sulfate include

mouthrinses, prebrushing rinses, and dentifrices.

Mouthrinses are designed to provide cosmetic and/or therapeutic benefits. The major desirable characteristics of sodium lauryl sulfate are its affinity for enamel surfaces and its ability to reduce surface tension, which theoretically should interfere with dental plaque formation and provide a clean tooth feeling. Prebrushing rinses rely on these characteristics for additional emulsifying activity, thereby maximizing dental plaque removal that is largely the result of bristle action. Finally, because of its properties as a surfactant, sodium lauryl sulfate is frequently used in toothpastes as a foaming agent. Its superior cleansing properties compared to soap as a toothpaste ingredient were reported as early as 1937 (Ref. 358).

In general, human mouthrinse studies have shown a moderate reduction in plaque formation in the test groups using sodium lauryl sulfate in various formulations, as compared to a control group using no sodium lauryl sulfate. No significant difference was observed between the test and control groups in gingivitis studies.

Typical plaque and gingivitis scores from two representative studies are shown below. The scores at the end of these studies represent plaque and gingivitis score changes from a zero baseline, following an initial prophylaxis:

TABLE 12.—PLAQUE AND GINGIVITIS SCORES FROM THE BARONS STUDY (REF. 359)

Study	Group (n)	Baseline	End
		Plaque scores	
Test Product	Test (13)	0	2.86
(0.3% SLS)	Water (13)	0	5.13
Net plaque reduction: 44%			
		Gingivitis scores	
	Test (13)	0	0.88
	Water (13)	0	0.90
Net gingivitis reduction: 2% (not significant)			

TABLE 13.—PLAQUE AND GINGIVITIS SCORES FROM THE PRETARA-SPANEDDA STUDY (REF. 348)

Study	Group (n)	Baseline	End
		Plaque scores	
Test Product	Test (7)	0	2.20
(0.3% SLS)	0.1% chlorhexidine (9)	0	2.43
	Water (9)	0	4.78
Net plaque reduction: 54%			
		Gingivitis scores	
	Test (7)	0	0.93
	0.1% chlorhexidine (9)	0	1.03
	Water (9)	0	1.17
Net gingivitis reduction: 21% (not significant)			

The statistically significant reductions in plaque scores in these studies, as compared to a water placebo, were not accompanied by a statistically significant reduction in gingivitis scores.

No convincing evidence exists to support the effectiveness of prebrushing rinses, because the net beneficial effect of the rinses as compared to placebo is clinically insignificant. One of the products tested in the Truelove study (Ref. 349) (see Table 14 of this document) contains a number of ingredients other than sodium lauryl sulfate (Ref. 360). However, sodium lauryl sulfate is listed as the only active component. The results of this study indicated that prebrushing rinsing with two rinses that contain sodium lauryl sulfate as the active ingredient is no more effective than rinsing with a suitable sodium lauryl sulfate-free placebo.

TABLE 14.—PLAQUE/GINGIVITIS SCORES FROM THE TRUELOVE STUDY (REF. 349)

Agent	Prebrush score	Postbrush score
Test product (0.25% SLS)	2.56	1.11
Other product (0.3% SLS)	2.94	1.23
Placebo	2.50	1.16

The results of the Emling study (Ref. 361) suggested a somewhat greater plaque score reduction with the test product containing 0.25 percent sodium lauryl sulfate than the placebo (see Table 15 of this document). However, gingivitis scores were not measured in this study or in several other unpublished studies with the same experimental protocol that produced similar results (Refs. 362 and 363).

TABLE 15.—PLAQUE SCORES FROM THE EMLING STUDY (REF. 361)

Agent	Prebrush score	Postbrush score
Test product (0.25% SLS)	3.12	2.05
Placebo	3.09	2.82

In addition, Beiswanger et al. (Ref. 364) were unable to detect a statistically significant difference in the degree of plaque reduction between active and placebo rinses.

Van Dyke *et al.* (Ref. 365) also monitored gingival changes under conditions of prebrushing rinsing. They reported statistically significant reductions of plaque scores for both the placebo and the test rinse as compared to baseline scores. Although there was a statistically significant advantage of the test rinse over the placebo (1.61 versus 1.84 mean score) at interproximal surfaces for plaque scores, these differences were not clinically significant. Further, there were no differences in gingivitis scores before and after treatment, or between test and placebo scores.

Kohut and Mankodi (Ref. 366) found no difference between test and placebo prebrushing rinses, either in the degree of plaque or gingivitis reduction. Similar results were reported by Singh (Ref. 367) and by Pontier et al. (Ref. 368) in children undergoing orthodontic treatment. In a 6-month clinical study, Lobene *et al.* (Ref. 369) failed to show that a test product containing 0.25 percent sodium lauryl sulfate was superior to a placebo in reducing plaque, gingivitis, or calculus.

The Subcommittee concludes that sodium lauryl sulfate is effective to facilitate the removal of food and other particulate material and provide a clean tooth feeling, primarily through its surfactant properties and its affinity for binding to tooth surfaces. Sodium lauryl sulfate appears to have a minor inhibitory effect on plaque formation, following an initial dental prophylaxis. Although sodium lauryl sulfate has antibacterial properties in vitro, it is not clear to what extent this antibacterial effect is exerted in vivo. The antiplaque effect of sodium lauryl sulfate is at best moderate. Sodium lauryl sulfate does not have a significant effect on gingivitis. The role of sodium lauryl sulfate as a facilitator of plaque removal when used in a prebrushing rinse is marginal and does not result in any beneficial clinical improvement, such as gingivitis reduction or inhibition of calculus formation. Sodium lauryl sulfate is a safe and effective foaming ingredient when used in toothpaste.

The Subcommittee concludes that sodium lauryl sulfate at 0.1 to 5 percent concentration in an oral rinse or dentifrice dosage is safe, but that there are insufficient data available to permit final classification of its effectiveness as an antiplaque and antigingivitis agent.

g. *Zinc citrate*. The Subcommittee concludes that zinc citrate is safe, but there is insufficient evidence to support its effectiveness as an OTC antigingivitis/antiplaque agent.

Zinc citrate has a chemical formula of $Zn_3(C_6H_5O_7)_2$ and is prepared from zinc carbonate and citric acid. It is described as a dihydrate, odorless powder, that is slightly soluble in water (Ref. 370). Based on the known abilities of zinc to inhibit crystal formation and of citrate to inhibit crystal aggregation, zinc citrate replaced zinc chloride (highly effective but with a disagreeable taste) as a toothpaste ingredient to inhibit dental calculus formation (Ref. 371). Zinc citrate trihydrate ($Zn_3(C_6H_5O_7)_2 3H_2O$) has been used to inhibit supragingival calculus formation.

i. *Safety*. Zinc is ubiquitous in our environment and is an essential trace element in humans. Its role in humans continues to be the subject of investigation. The overall safety of zinc citrate has been well and extensively documented (Ref. 372). Acute toxicity studies in animals have shown zinc citrate to be only slightly toxic. Zinc citrate fed to rats for up to 13 weeks produced toxic effects only at high levels. No toxic effects were observed when toothpaste containing up to 10 percent zinc citrate was fed to rats and dogs for up to 18 months. In humans, zinc salts are considered relatively nontoxic (Ref. 372).

Zinc citrate had no adverse effects on fertility, the fetus, or neonate in rats and rabbits (Ref. 372). This finding correlates with published findings on other zinc salts. No mutagenic effects have been reported from in vivo studies. Zinc does not have genotoxic effects or pose a carcinogenic hazard at levels normally found in the body (Ref. 372). The oral irritation potential of toothpastes containing zinc citrate is no greater than that of other marketed toothpastes.

ii. *Effectiveness*. The Subcommittee reviewed five short-term clinical studies, two 6-month studies, and a 3-year trial assessing the effect of zinc citrate on gingivitis (Ref. 373). The five studies had in common a 21-day experimental period in which subjects, following a 4-week period of tooth cleaning and oral hygiene instruction, refrained from brushing one lower quadrant of teeth. An impression of each lower tooth arch was made and a plaster mold prepared. A plastic ''tooth shield'' was heated and vacuum fitted to

the plaster models. Subjects were instructed to place a measured quantity of dentifrice into the indentations in the tooth shield twice daily prior to its insertion in the mouth, and brush the remaining teeth. Plaque and gingivitis were assessed after 21 days. Various concentrations of zinc citrate in toothpaste or other ingredients alone or in combination with zinc citrate were used as well as placebos, which were not as effective as active ingredients. Because these studies were not randomized clinical trials, they cannot be considered as evidence of the effectiveness of zinc citrate.

The first 6-month study by Hefti and Marks (Ref. 374) was conducted to evaluate the relative effectiveness of a hydrogen peroxide/baking soda/fluoride/zinc citrate dentifrice with a commercially available fluoride dentifrice and a commercially available fluoride antitartar dentifrice. This was essentially a supragingival calculus study where subjects were selected based on having a score of at least 6.0 on the Volpe-Manhold Calculus Index at the time of screening. Clinical exams during the trial period were done at 45, 90, and 180 days. The Modified Gingival Index by Lobene et al. (Ref. 112) was used for gingival assessment. Only simple means for the 6 months assessment were given for the 3 groups of 60 to 63 subjects. A simple p value was given, indicating the multiingredient product and the other antitartar toothpaste group had statistically lower scores than the fluoride-only commercially available toothpaste. Three means were given for 45 and 90 days, plus one p value, showing similar results. No information was provided about subject characteristics, inclusion or exclusion criteria other than Volpe-Manhold Calculus Index scores, examiners, compliance, indicators of measurement error or uncertainty, or blinding. The conclusions concerning zinc citrate effectiveness were based on a multiagent product compared to other agents/ingredients.

The second 6-month clinical study (Ref. 375) included 295 subjects selected from a population of 330 adults of which 311 fulfilled strict dental and medical health requirements. No further details on health requirements were given. No information was provided about the study population, e.g., age, sex, education, and socioeconomic status. Inclusion criteria included a gingival index score greater than 0.5 but less than 2.5 on a scale of 0 to 3. One-third of the qualifying subjects were selected for plaque collection, which was performed prior to disclosing for the plaque assessment. There was no information on how these subjects were selected.

The products used were described as supplied by the sponsor in identical two-chamber, 5.2 oz pump dispensers, each with one of three three-letter codes. The report (Ref. 375) describes the three as ''negative control dentifrice,'' ''experimental dentifrice,'' and ''experimental dentifrice.'' An accompanying summary identified the products only as ''dual-phase dentifrices containing stannous salts and/or zinc citrate.'' One of the three-letter codes was identified only as ''the zinc citrate-containing dentifrice.'' Thus, there was no information about the composition and concentration of ingredients or details about differences in color, odor, and taste in the products tested. The Subcommittee does not believe this study adhered to strict criteria for a double-blind study because the following appeared in the report: ''Except for some complaints about the taste and staining associated with experimental dentifrice 'ABC,' the products were favorably received.'' These complaints were associated with only one of the three tested products. This suggests that one product differed from the others in taste and staining and, therefore, the study was not a double-blind study.

Examiners were described only as ''experimental examiners, who participated in a calibration exercise prior to initiating the investigation, performed the same assessments at each examination.'' The report did not discuss the number of examiners and their background, whether calibration was successful, or testing for intra-examiner and inter-examiner reliability.

Mean gingival index scores plus standard error were given for each of the three groups at baseline, 3 months, and 6 months (279 of 295 subjects completed 6 months). All scores were reduced from baseline at 3 and 6 months. The dentifrice containing zinc citrate was statistically significantly different ($p<0.03$) from the ''control'' group. Mean scores at 3 months were 0.87±.02 for the control dentifrice, 0.83±0.2 for the test dentifrice without zinc citrate, and 0.81±.02 for the test dentifrice containing zinc citrate. At 6 months the scores were 0.92±0.2 for the control dentifrice, 0.86±0.2 ($p<0.04$) for the test dentifrice without zinc citrate, and 0.85±.02 ($p<0.04$) for the test dentifrice containing zinc citrate. The study does not provide evidence that a clinically significant improvement in gingival index scoring was due to zinc citrate.

The 3-year trial (Ref. 376), of which results from the first 2 years were submitted, was a caries study. The main objectives of the trial were to establish the reduction of caries increments caused by increasing the level of sodium monofluorophosphate and to investigate whether the inclusion of 0.5 percent zinc citrate affected caries increments. Three thousand children with a mean age of 12.5 years and all within a 1-year age range were recruited. Two clinicians assessed all subjects, who were then randomly assigned to one of six toothpaste groups. One-half of the subjects used a toothpaste containing zinc citrate. Plaque (using Greene and Vermillion's Simplified Oral Health Index (OHI-S)) and gingivitis (Loe and Silness Gingival Index) were assessed each year. Six teeth were assessed: One molar, premolar, and incisor in each arch, at four surfaces on each tooth.

Differences between cumulative mean scores for groups using toothpastes with and without zinc citrate were calculated. One examiner showed nonstatistically significant differences for years 1 and 2 and a second examiner showed statistically significant differences. When pooled together, the small differences were statistically significant. There was no other information about examiner calibration or testing for intra and interexaminer reliability. Clinically significant effects due to zinc citrate could not be determined from this study.

The Subcommittee's criteria for data submitted from randomized clinical trials include presenting information on all of the major study components, e.g., the protocol (study population, agents, outcomes, rationale for statistical analysis), methods of randomization, concealment of allocation to study group, and method of blinding. Results should be presented with appropriate indicators of measurement error or uncertainty, avoiding dependence solely on statistical hypothesis testing, such as the use of p values, which fail to convey important quantitative information. Based on these criteria, the Subcommittee concludes that the data submitted were insufficient to permit final classification of the effectiveness of zinc citrate as an OTC antigingivitis/antiplaque agent.

2. Category III Combinations of Active Ingredients

Data to demonstrate safety and effectiveness as an antigingivitis/antiplaque agent will be required in accordance with the general guidelines on safety and effectiveness in section II.H of this document.

Alkyl dimethyl amine oxide and alkyl dimethyl glycine

Hydrogen peroxide and povidone iodine

Hydrogen peroxide and sodium bicarbonate

Hydrogen peroxide, sodium citrate, sodium lauryl sulfate, and zinc chloride

Peppermint oil and sage oil

Polydimethylsiloxane and poloxamer

Stannous pyrophosphate and zinc citrate

a. *Alkyl dimethyl amine oxide and alkyl dimethyl glycine*. The Subcommittee concludes that there is insufficient evidence to support the safety and effectiveness of the combination of alkyl dimethyl amine oxide and alkyl dimethyl glycine as an OTC antigingivitis/antiplaque agent. This combination consists of two amphoteric (having both acidic and basic properties) quaternary ammonium inner salt surfactants said to have broad spectrum antimicrobial activity.

i. *Safety*. An acute oral toxicity study (Ref. 377) of a 3-percent solution of alkyl dimethyl amine oxide and alkyl dimethyl glycine calculated that the LD_{50} in Sprague-Dawley rats was greater than 6,000 mg/kg. Necropsy observations included slight intestinal hemorrhage, slight liver discoloration, and slight to severe lung congestion.

An additional acute toxicity study in beagle dogs (Ref. 378) was difficult to evaluate because the dosages were stated in mL/kg but the concentration of the solution was not stated. Although there did not appear to be a constant pattern at necropsy, all of the dogs displayed abnormal findings, such as cortical congestion of the mesenteric lymph nodes, white nodules on the gall bladder mucosa, and consolidation of the lungs with a yellow-colored mucoid material in the bronchi.

A series of dermal toxicity studies was carried out. Again, because the concentration of the liquid used was not stated, these studies were difficult to evaluate. In one study (Ref. 379), the dermal toxicity of a 3-percent solution of the combination of alkyl dimethyl glycine and alkyl dimethyl amine oxide was evaluated on abraded skin of rabbits. Two of 20 animals displayed minimal reaction. An additional study (Ref. 380) reported that 3.6 percent of an applied dose was absorbed through rabbit skin.

Two dermal sensitization studies were carried out in guinea pigs (Refs. 381 and 382) and appeared to have diverse results. In one study (Ref. 381), the investigator concluded that there was no evidence suggesting the combination of these ingredients can act as a sensitizer in the guinea pig. However, it was unclear what concentration of the test material was used. In the second study (Ref. 382), it was concluded that repeated topical exposures of guinea pigs to a 3–percent solution of these ingredients has the potential to induce mild dermal sensitization.

Based on the results of a *Salmonella*/microsome mutagenesis assay (Ref. 383), the authors concluded that the combination of alkyl dimethyl amine oxide and alkyl dimethyl glycine inhibits the growth of microorganisms at some concentrations. Although small increases were observed in several strains of *S. typhimurium*, the authors stated that these increases were not reproducible and were attributed to random fluctuations that do not represent a mutagenic response to the test product. The test, therefore, has some limitations.

Eye and vagina1 irritant tests have also been conducted. A 3-percent solution of alkyl dimethyl amine oxide and alkyl dimethyl glycine was judged to be a mild irritant in the eyes of dogs and a severe irritant in rabbits (Ref. 384). In an additional study conducted by a different institution, it was concluded that a 12.5-percent solution was not an irritant to rabbits. Results from vaginal irritation studies (Ref. 385) concluded that these ingredients produced an ''acceptable'' vaginal irritation score. However, it was unclear which concentrations were tested and what is an ''acceptable'' score. Six preparations appear to have been examined, but no information was presented on how they differed in composition.

The data also included a series of studies (Refs. 386, 387, and 388) evaluating a 10-percent solution of alkyl dimethyl amine oxide and alkyl dimethyl glycine as a body wash in nursing home patients. The evaluations appear to be largely subjective or gathered from interviews. Adverse effects were not observed.

Dentists gave the combination of these ingredients to subjects to use as a mouthrinse (Refs. 389 and 390). Overall adverse effects, including tingling, mucosal irritation, stain, and a peppery sensation on the tongue, were reported by 0.5 to 0.8 percent of users. Other dentists (Ref. 391) reported adverse effects in 1.3 percent of subjects.

The effects of the combination of these ingredients on mammalian cells were examined using a chromium release assay from human leukemic cells (H6–60). The release of chromium occurred at concentrations of 0.025 to 0.005 percent. As the report notes, ''these findings are of some concern since the effective window approximates the MIC for several bacterial species'' (Ref. 392).

ii. *Effectiveness*. A number of studies have been carried out to assess the effects of this combination on the growth of oral bacteria and on the ability of oral microorganisms to produce acid from glucose.

The combination of alkyl dimethyl amine oxide and alkyl dimethyl glycine exhibits an antimicrobial effect against a wide range of microorganisms (Ref. 393). *Lactobacillus casei* is highly susceptible and is inhibited by as little as a 0.0004-percent solution. Several isolates of *Pseudomonas* are highly resistant to the combination. In general, the effect against gram-positive organisms was independent of pH. In contrast, the effect against gram-negative organisms was influenced by pH values. A 0.5-percent concentration of these ingredients completely inhibited bacterial glycolysis for 7 hours and inhibited the adherence of *S. sobrinus* to michrome wires. A lower concentration (0.05 percent) had less effect.

Twelve subjects (Ref. 394) rinsed with various concentrations of alkyl dimethyl amine oxide and alkyl dimethyl glycine and other preparations with only 2 days allowed between testing each material. Concentrations of 0.1 percent or higher reduced the population of total cultivable flora and total *Streptococcus* populations for at least 1 hour post rinse. Concentrations of 0.2 and 0.5 percent inhibited glycolysis in salivary sediment for several hours.

A clinical study involving 84 females and 42 males (aged 20 to 49) used a 0.25-percent solution (pH 6.8) of this combination (Ref. 395). Subjects were divided into one of three groups using a placebo, the test ingredients, or a positive control. Gender distribution was not disclosed. Following a complete prophylaxis, subjects rinsed twice daily for 6 weeks with 20 mL of solution. Subjects were instructed to continue their normal oral hygiene throughout the study. Plaque was assessed using Turesky modification of the Quigley-Hein Index. Mean plaque scores at the end of the study were as follows: Placebo, 2.53 ± 0.56 (2.44 ± 0.38), test ingredients, 2.05 ± 0.58 (2.45 ± 0.36), and positive control, 1.96 ± 0.33 (2.46 ± 0.31). An F test (test for equality of variances) comparison of the final three numbers showed statistica1 differences. An F test between the test solution and the positive control showed no statistically significant difference. No other statistical tests were reported. Gingivitis was not assessed.

A brief report (Ref. 396) claimed that a toothpaste containing these

ingredients reduced plaque formation by 43 percent in 15 subjects who used these ingredients for 7 days. Gingivitis apparently was not assessed. The report lacked essential information.

In a combined animal and human study (Ref. 397) and a separate human study (Ref. 398), a toothpaste containing 1 percent of the combination of alkyl dimethyl amine oxide and alkyl dimethyl glycine applied topically three times weekly had no effect in preventing caries.

In a more recent single-blind, randomized, crossover study in 20 subjects (Ref. 399), the effects of four ingredients, including the combination of alkyl dimethyl amine oxide and alkyl dimethyl glycine, were compared with saline in preventing plaque regrowth. Subjects rinsed twice daily for 1 minute and suspended normal oral hygiene measures. Plaque was scored using a plaque index and plaque area assessment. The combination of alkyl dimethyl amine oxide and alkyl dimethyl glycine was significantly less effective than the other three agents tested, but was more effective than saline. Gingivitis was not assessed.

Based on the data submitted, the Subcommittee concludes that there is insufficient evidence to support the safety and effectiveness of the combination of alkyl dimethyl amine oxide and alkyl dimethyl glycine as an OTC antigingivitis/antiplaque agent.

b. *Hydrogen peroxide and povidone iodine*. The Subcommittee has determined that there is insufficient evidence to support the safety and effectiveness of the combination of hydrogen peroxide and povidine iodine as an OTC antigingivitis/antiplaque agent.

i. *Safety*.

The Subcommittee concludes that hydrogen peroxide is safe at concentrations of up to 3 percent. Because the final concentration of hydrogen peroxide in this combination is 1.5 percent when the separately packaged solutions are mixed, the Subcommittee considers this portion of the combination to be safe. The povidone iodine component of the combination (5 percent final concentration), however, raises several safety concerns, including acute and chronic toxicity.

1. *Acute toxicity study*. An acute toxicity study (Ref. 400) was performed on rats to determine the LD_{50} iodine concentration. Ten animals were dosed with 5 g/kg with no fatalities occurring. The data established that povidone iodine is not considered toxic when the LD_{50} is greater than 5 g/kg. The only noted toxic effect at this level was hydronephrosis (distention with urine) of the kidneys of two male rats.

2. *Oral mucosal toxicity study*. Oral mucosal toxicity was also examined in rats (Ref. 401). A solution containing 1.5 percent hydrogen peroxide and 5 percent povidone iodine was applied three times daily for 7 days to the oral mucosa of 12 albino rats. Two other groups of 12 rats were exposed to the components individually. While there were animals in each group that did not gain weight normally, the differences between the groups were not significant. In the group that received the combination of ingredients, 5 of the 12 animals showed signs of acute iodine toxicity, including lethargy, diarrhea, and abnormalities in the GI tract. These signs suggest possible acute toxicity in humans due to iodine overdose. These abnormalities were not noted in the two groups exposed to hydrogen peroxide or povidone iodine solutions individually. No negative control group was included.

3. *Acute dermal toxicity study*. In an acute dermal toxicity study, a 10-percent povidine iodine solution mixed with 3 percent hydrogen peroxide at 2 g/kg of body weight was applied to 10 albino rats (Ref. 402). Skin reactions were recorded as slight, but 8 of 10 animals showed lethargy, nasal discharges, diarrhea, and other signs of GI disturbances. All 10 animals survived, showing only mild dermal irritation. The investigators defined the test mixture as nontoxic because the LD_{50} was greater than 2 g/kg of body weight.

4. *Eye irritation study*. An eye irritation study was conducted on six albino rats by placing a standard mixture of 10 percent povidine iodine and 3 percent hydrogen peroxide (Ref. 403) into the conjunctival sac and scoring by the Draize technique at 1, 2, and 3 days after dosing. The test mixture was determined to be an irritant, causing iritis and moderate conjunctival irritation in five of six animals.

5. *Chronic toxicity study*. Chronic toxicity is also of concern because of the activity of iodine on the thyroid. A 6-month prospective study in 50 subjects to assess thyroid function and iodine levels following prolonged exposure to the mouthrinse showed that iodine levels were significantly elevated in test subjects with increased protein bound iodine in blood and in urine samples (Ref. 404). In general, thyroid function tests remained within normal limits. These tests included serum thyroxine (T4), free T4, triiodiothyronine (T3), and free T4 index measurements. A small but significant rise in the serum thyroid stimulating hormone (TSH) was consistently noted. The investigators suggested that this small increase in serum TSH should be considered a normal physiological adaptive response to increased iodine intake and had no adverse effects on the subjects. While the study was a good first step in establishing the safety of chronic use of the test solution, there were several concerns. The total number of healthy subjects was relatively small and may not reveal possible side effects in a larger population. While the investigators considered increased TSH without concomitant serious side effects as a sign that subjects were able to tolerate increased iodine, an alternative interpretation is that the increased TSH was an early indication of a thyroid system that is not functioning properly. A larger and perhaps longer study is needed.

6. *Chronic use test in compromised thyroids*. Although a second much smaller study examined the effects of chronic use of a mouthrinse containing hydrogen peroxide and povidone iodine in subjects with compromised thyroids, the number of subjects was completely inadequate to establish possible side effects.

7. *Mutagenicity tests*. Tests to determine the mutagenicity of povidone iodine were carried out using the Salmonella/microsome mutagenesis assay, a micronucleus test in rats, and a rat hepatocyte DNA repair assay (Refs. 405, 406, and 407). While the tests indicated cell toxicity, they did not indicate a mutagenic effect. A cytotoxicity study examining the cytotoxic effects on Chinese hamster ovary cells was also reported (Ref. 408). The study concluded that the combination rinse is cytotoxic at a concentrations of 2,500 μg/mL. The report indicated that when a metabolic activation mixture with the appropriate buffer and cofactors was added to the assay, the test rinse was no longer considered cytotoxic. The report did not elaborate on the possible ramifications of these results.

In order to evaluate the acute toxicity studies submitted, the Subcommittee examined iodine toxicity in general. Acute toxicity of iodine tincture (2 percent iodine and 2.4 percent sodium iodine in a 50 percent ethanol solution) has been recorded at levels relevant to the concentration of povidone iodine (5 percent) in this combination. Fatal events have occurred when as little as 30 mL of tincture of iodine have been ingested (Ref. 409). Acute toxic effects produce local actions in the GI tract. Iodine is corrosive, but is also readily inactivated by foodstuffs. When large concentrations of iodine are ingested,

resulting shock and tissue hypoxia have been noted (Ref. 409). Ingestion of lesser amounts can cause gastroenteritis, abdominal pain, and diarrhea that may be bloody. Nausea and vomiting are common with ingested iodine.

The current product labeling recommends that children under 12 be supervised while using the product and warns against use by pregnant or nursing mothers, those with iodine sensitivity, and those with a history of thyroid disorder. Because of the potential toxic side effects, the labeling should include a warning that the product should not be used by children, women of child-bearing years, or anyone suffering from a thyroid disease, disorder, or ailment. Subjects considering long-term use of these ingredients should consult their physician to determine if any conditions exist that might contraindicate use.

ii. *Effectiveness*.

1. *Six-month studies*. Two 6-month studies (Refs. 410 and 411), a 3-week study (Ref. 412), a 6-week study (Ref. 413), and a brief review of the antimicrobial effects of mouthrinses on dental plaque (Ref. 414) were submitted. The 6-month studies (Refs. 410 and 411) were designed similarly, using subjects admitted according to common exclusion criteria. Subjects received a thorough prophylaxis and were then assigned to one of four groups using a test rinse containing hydrogen peroxide and povidone iodine, a rinse containing only one of these ingredients in distilled water, or a distilled water placebo. Because the subject pool was divided into four groups, each group had a relatively limited number of subjects. Ninety total subjects completed one study (Ref. 410) with 23 in the test rinse group, and 96 subjects completed the other study (Ref. 411) with 23 in the test rinse group. Clinical assignments included measurements of plaque using the Turesky modification of the Quigley-Hein Plaque Index and the Papillary Bleeding Scoring, which attempts to quantitatively assess inflammation and bleeding at the interproxima1 sites.

Several troubling aspects of the protocol jeopardized the value of the studies from the start. The overall sample size was immediately halved by including groups that used only hydrogen peroxide or only povidone iodine. The control rinse was substantially different from the test rinse and did not contain a placebo vehicle. The protocol for both studies included professional subgingival irrigation at 3-week intervals throughout the study. Further, subjects were instructed not to rinse, drink, or eat anything for 30 minutes following the rinsing procedure.

Results from the two 6-month studies failed to provide convincing clinical data in support of the tested ingredients. For example, while one study showed borderline significant plaque index score differences, the other study did not. Neither study reported the overall gingival index (bleeding index) scores. It appears that there were no significant differences overall for the gingival index in either study. Instead, only scores for sites greater than or equal to three were chosen for analysis. While both studies suggested that significant differences could be determined in this limited and skewed selection of sites, p values for these comparisons were unclear or not reported. Because use of the test solution did not significantly affect plaque buildup in at least one of the studies, it is possible that the positive effect on the gingival condition was due to the subgingival irrigation professionally administered every 3 weeks during the test period. If the test solution altered the subgingival flora but did not significantly change the supragingival flora, the most likely contributing factor would be the professional irrigation.

Further, the two studies were tabulated differently and the results were somewhat difficult to compare. One study compared sites while the other study examined differences between subjects. The number of sites used in these analyses was unclear or unstated. The investigators in one study chose sites over subjects for analysis because of the variation in the number of sites between subjects with a bleeding index greater than 3. Therefore, it is possible that one or only a few subjects had many sites and the remaining subjects had few sites that qualified. Such a distribution could produce results that realistically represent only a few subjects within the group rather than the group itself. As with several other important aspects of these studies, p values and standard errors for specific comparisons were often unclear or unstated.

The studies included a limited number of samples for microbiological examination. The investigators in both studies utilized selective media along with other microbiological assays. Both study reports indicated that opportunistic pathogens (*Candida* and enteric bacteria) did not establish themselves in any of the test groups sampled. The test solution samples tended to show fewer presumed periodontal pathogens compared to control samples. However, the number of periodontal pathogens was generally quite low or absent depending on the species studied. While the microbiological data hold some interest, the use of professional subgingival irrigations throughout the studies made interpretation of the microbiology data difficult.

The design of these studies made definitive conclusions very difficult, with no consistent or convincingly significant clinical effect on plaque or gingivitis. The toxicology data suggested that the combination is safe, but doubts linger. An appropriately sized study of healthy and thyroid-compromised subjects should be considered using a placebo that more closely resembles the test product. Subjects should not be instructed to refrain from eating, drinking, or rinsing and professional irrigation should not be included, as such procedures might significantly alter the results.

2. *Three and 6-week studies*. Two short-term studies of 3 and 6 weeks (Refs. 412 and 413) showed significant improvement in the clinical parameters reported. However, several ingredients reviewed by the Subcommittee, including some formulations of hydrogen peroxide, have shown positive short-term results only to fall short in long-term studies.

Based on these studies, the Subcommittee finds that there is insufficient evidence to support the safety and effectiveness of the combination of hydrogen peroxide and povidone iodine as an OTC antigingivitis/antiplaque agent.

c. *Hydrogen peroxide and sodium bicarbonate*. The Subcommittee concludes that the combination of sodium bicarbonate and hydrogen peroxide at concentrations up to and including 3 percent hydrogen peroxide is safe, but there are insufficient data available to permit final classification of the effectiveness of the combination as an antigingivitis/antiplaque agent.

i. *Safety*. Hydrogen peroxide can produce hydroxyl radicals in the presence of iron (Fe+2) or copper (Cu+1) (Refs. 188 and 189) and in vitro studies have shown that sister chromatic exchanges can be produced by hydroxyl radicals. Experimental and clinical data are sparse demonstrating a significant mutagenic effect with the combination of hydrogen peroxide and sodium bicarbonate in oral health care products. Experimental and clinical data, however, do not demonstrate a significant mutagenic potential with the combination of hydrogen peroxide and sodium bicarbonate in oral health care products (Refs. 145, 188, and 189). The rapid decomposition of hydrogen peroxide in the presence of sodium

bicarbonate (Ref. 145) further reduces the likelihood of a mutagenic effect occurring with combination products.

A 1989 mutagenicity study by Kuhn et al. (Ref. 415) tested varying concentrations of a gel containing levels of hydrogen peroxide up to 100 μg/plate in a bacteriological assay for toxicity and mutagenicity on several strains of *S. typhimurium*. The results showed no toxic or mutagenic effects on the strains tested, which was approximately 100 times greater than the optimal mutagenic response seen with aqueous hydrogen peroxide. This result is in contrast to other studies using strains of *S. typhimurium* that showed mutagenic action associated with hydrogen peroxide (Refs. 163, 168, and 416). This result is also in agreement with studies conducted with peroxide formulated in dental products that are uniformly not mutagenic in oxidant-sensitive bacterial strains (Refs. 172 and 417).

After 1 minute of brushing, recovery of hydrogen peroxide in the presence of baking soda was less than 5 percent of the amount introduced into the oral cavity (Ref. 145). Identical results on hydrogen peroxide decomposition were seen in control subjects and subjects with impaired salivary flow.

Using a rat animal model, a combination of sodium bicarbonate and hydrogen peroxide incorporated into a toothpaste vehicle was tested for oral mucosa irritancy by Meyers et al. (Ref. 418). The particular formulation was found to be a mild-to-moderate irritant. However, the test toothpaste was found to be less irritating compared to a common fluoridated toothpaste used as a control. Unfortunately, the concentrations of ingredients did not appear to be listed, including the concentration of sodium bicarbonate and hydrogen peroxide. These results do not agree with those reported by Marshall et al. (Ref. 184), in which no irritation was found to the oral mucosa of hamsters administered a dual phase hydrogen peroxide and sodium bicarbonate dentifrice containing 0.75 percent or 1.5 percent hydrogen peroxide and 5 percent or 7.5 percent sodium bicarbonate once-daily, five times per week for up to 20 weeks.

Two animal studies examined the potential for oral mucosal irritation by hydrogen peroxide in combination with sodium bicarbonate (Ref. 184). No mucosal irritation was observed after administration of a hydrogen peroxide and baking soda dentifrice once daily, five times a week for 20 weeks. These results support clinical and consumer studies that show no evidence of oral irritation following use of dentifrices containing a combination of these ingredients. A study by Kuhn et al. (Ref. 419) used a combination of 10 percent sodium bicarbonate and 1.5 percent hydrogen peroxide. The study included exposure of the test animals to DMBA, a known carcinogen, and evaluated if any of the test compounds (including this combination) resulted in additional carcinomas. The test and control compounds were administered in a 20-week cheek pouch mucosal irritation study and no additional carcinogenic effects from the test combination were found. These results and those seen in a second hamster bioassay (Ref. 184) are contrary to those of Weitzman et al. (Ref. 183) who found that, when combined with DMBA, hydrogen peroxide, only at a concentration of 30 percent, appeared to augment the carcinogenic effects associated with DMBA. No augmentation of the carcinogenic effects of DMBA was seen with 3 percent hydrogen peroxide in the Weitzman study (Ref. 183), whose results support the previous observations that concentrations of hydrogen peroxide of 3 percent or less are safe for use in the oral cavity.

In a 9-month human trial with concentrations of 10 percent sodium bicarbonate and 1.5 percent hydrogen peroxide used as a dentifrice, Truelove (Ref. 420) found no increase in yeast concentrations in test subjects compared to subjects using a standard fluoridated dentifrice.

There are reports in the literature of excessive use of these compounds producing marked gingival detrimental changes, although these lesions appear to be easily correctable (Refs. 421 and 422).

ii. *Effectiveness*. The value of the combination of hydrogen peroxide and sodium bicarbonate has led to a continuing debate within the dental research and clinical communities. An in vitro MIC and minimal bactericidal concentration (MBC) study found that both ingredients were weak bacteriocidal agents, with sodium bicarbonate requiring extremely high dosages to cause bacterial cell death (Ref. 423). Varying outcomes resulted from the concentration of ingredients, with some mixtures inhibiting/killing while other concentrations produced a synergistic effect. In one study, a combination of 3 percent hydrogen peroxide, 0.5 g of sodium bicarbonate, and 10 g sodium chloride was tested on 10 experimental and 10 control subjects who had moderate periodontitis and were carefully scaled and root planed at the beginning of the study (Ref. 424). The experimental subjects had the test ingredients administered at home with a toothbrush and at biweekly professional irrigations. Sites in the test group also received iodine applications. The results indicated that following scaling and root planing, and with a carefully monitored oral hygiene regimen including sodium chloride and iodine in addition to the hydrogen peroxide and sodium bicarbonate, a reduction of several clinical periodontal parameters occurred after 3 months of treatment. This study suggested a significant effect on the oral flora could be achieved by subgingival irrigation with these chemicals.

In a 3-week study (Ref. 425), a 1.5-percent hydrogen peroxide and a 2-percent sodium bicarbonate mouthrinse was tested in a positive and negative parallel-control study. The results indicated significant control of gingivitis and gingival bleeding compared to the negative control. The rinse compared favorably to the positive control 1.2 percent chlorhexidine rinse. The Subcommittee found that the study only evaluated efficacy up to 3 weeks, and long-term results are unknown.

Using a split-mouth design, Greenwell et al. (Ref. 426) tested the effect of this combination (hydrogen peroxide, sodium bicarbonate, and salt water) against standard oral hygiene methods. The effects on commonly monitored indices suggested no significant effect over the standard oral hygiene control except where initial therapy was not instituted. However, these subjects were diagnosed with treated or untreated periodontitis, and the study was limited to 8 weeks.

In a similar study, four subjects with early periodontitis used either a fluoridated paste or an experimental paste containing 3 percent hydrogen peroxide and sodium bicarbonate in a splitmouth study design. Over the 3-week test period, no discernible differences between the groups could be identified (Ref. 427). Similar results were found in a 3-month study in which the test ingredients (hydrogen peroxide and sodium bicarbonate) were applied with a toothpick (Ref. 428).

In a 2-year study in which salts and hydrogen peroxide mixture was compared to conventional oral hygiene methods, no discernible differences could be found using phase contrast microbiological parameters (Ref. 429). In another 2-year study, no positive clinical effects were discernible from the use of the combination of test ingredients (hydrogen peroxide, sodium bicarbonate, and sodium chloride) compared to conventional oral hygiene methods (Ref. 430). The 4-year data from the same subject group showed the same results as seen at 2 years (Ref. 431). As in the study noted above (Ref.

426), the subjects in this large-scale, long-term study had diagnosed early periodontitis. Keyes et al. (Refs. 432 and 433), in uncontrolled and poorly documented reports, indicated reductions in signs and symptoms associated with periodontal diseases when using a regimen consisting of a thick mix of sodium bicarbonate slightly moistened with a few drops of water and 3 percent hydrogen peroxide.

Because of a lack of properly designed studies showing conclusively that the combination of hydrogen peroxide and sodium bicarbonate is effective, this combination of ingredients does not appear to present any added benefit to oral hygiene products. Further, most reports indicated that the two ingredients were no better at controlling plaque and gingivitis than products currently on the market which do not contain these ingredients. Moreover, many of the published references exploring the effects of these ingredients tested small numbers of subjects, did not employ controls, and/or used subjects with inappropriate disease entities, such as mild to moderate periodontitis. Many of the published references instituted a variety of professional cleanings, irrigations, instructional oral hygiene sessions, and additional possibly active ingredients during the test periods, thus further clouding the already contradictory results. Several studies did not disclose the concentrations of either ingredient, making it difficult to make conclusions.

d. *Hydrogen peroxide*, sodium citrate, sodium lauryl sulfate, and zinc chloride. The Subcommittee concludes that the combination of these ingredients is safe, but there is insufficient evidence to permit final classification of its effectiveness as an OTC antigingivitis/antiplaque agent. The Subcommittee is aware of three formulations of a combination of hydrogen peroxide, sodium citrate, sodium lauryl sulfate, and zinc chloride. All of the active ingredients have potentially useful properties when included in a mouth rinse.

Hydrogen peroxide (0.595 to 1.5 percent). Hydrogen peroxide is used for its antibacterial and foaming properties (see section III.C of this document).

Sodium citrate (0.024 to 0.12 percent). Sodium citrate is used as an astringent and to enhance the antibacterial activity of zinc chloride.

Sodium lauryl sulfate (0.06 to 0.15 percent). Sodium lauryl sulfate is used for its emulsifying and antiplaque formation properties (see section III.C of this document).

Zinc chloride (0.016 to 0.08 percent). Zinc chloride is used for its antibacterial properties and its ability to reduce plaque accumulation and acid production by plaque bacteria. Zinc has also been shown to be effective in inhibiting calculus formation by interfering with the conversion of amorphous calcium phosphate to more crystalline calcium phosphate compounds and their growth (Ref. 434). The antibacterial effect of zinc salts may be enhanced in the presence of sodium lauryl sulfate.

i. *Safety*. Because the above ingredients are used in combination, the safety and efficacy of these ingredients must be examined under conditions of combined use.

Toxicity in animals. Acute oral toxicity tests in rats (Ref. 435) indicated that one of the three formulations (it is not clear from the protocol which one), is relatively nontoxic. The purpose of the study was to assess the toxicity of the combination of ingredients administered orally as a single dose to Sprague-Dawley rats, followed by a 14-day observation period. The combination was administered by oral gavage to five male and five female rats at a dose of 40 g/kg of body weight. Over the following 14 days all animals survived in apparent good health, although they exhibited hunched postures and loose stools for the first 2 days. No abnormal findings were observed at necropsy. This dose is considerably higher than the likely intake by subjects using these ingredients in a rinse.

In another study on the effect of topical application of this formulation to hamster cheek pouches, 76 hamsters were divided into 3 groups of 22 animals each, with equal numbers of males and females, and a fourth group of 10 animals. The test group received daily topical applications of the test formulation to their cheek pouches for a 30-day period. The negative control group received comparable applications of water. The positive control group received 5 percent sodium lauryl sulfate. An additional group of 10 animals received a fixed combination of essential oils and water. At the end of the 30-day period, the cheek pouches were examined clinically and histologically. The results indicated no evidence of mucosal irritation in the form of epithelial damage, inflammation, hyperplasia, atrophy, or hyperkeratosis when compared to the water control (Ref. 436).

Another hamster study of 30-days duration compared topical applications of the test formulation to abraded and non-abraded hamster cheek pouches with application of 0.12 percent chlorhexidine gluconate, 1, 2, and 3 percent hydrogen peroxide, 5 percent sodium lauryl sulfate, and tap water. The animals on the test formulation gained weight normally and did not demonstrate any evidence of mucosal irritation in the form of inflammation, epithelial ulceration, hyperplasia (abnormal multiplication of cells in a tissue), atrophy, or hyperkeratosis (enlargement of the keratin layer due to increase in cell size), as compared to the water control. The test formulation did not interfere with the healing of abraded pouches (Ref. 436).

ii. *Effectiveness*.

1. *Mechanism of action*. It is not clear how this complex mixture behaves under conditions of normal use. One formulation contains 0.6 percent hydrogen peroxide and is dispensed in a single bottle. In the other two formulations, the rinses are dispensed in two bottles, one of which contains hydrogen peroxide. The directions state that the contents of the two bottles should be mixed just prior to rinsing. According to the data, these latter two formulations have 2.5 to 3 times the concentration of the active ingredients found in the first formulation and are combined with 1.5 percent hydrogen peroxide versus 0.6 percent hydrogen peroxide used in the first formulation. One of the latter two rinses also has 5 times as much zinc chloride as the first rinse. The proportions of the ingredients vary among the three formulations, but are generally found in relatively low concentrations. The concentration ranges for the active ingredients are as follows: Hydrogen peroxide, 0.595 to 1.5 percent; sodium citrate, 0.024 to 0.12 percent; sodium lauryl sulfate, 0.06 to 0.15 percent; and zinc chloride, 0.016 to 0.08 percent (Ref. 437).

2. *In vitro studies*. Study 1 evaluated the effect of the combination formulation on acid production by *S. mutans* and included three experimental groups: (1) *S. mutans* in an enriched growth medium (control), (2) *S. mutans* in an enriched growth medium exposed for various durations to the combination formulation with a 1:4 dilution, (3) *S. mutans* in an enriched growth medium exposed for various durations to the combination formulation with a 1:8 dilution. After a 5-minute exposure, the cells were centrifuged, washed, resuspended in combination formulation-free medium, and incubated. The viability of the bacterial cells was not affected by the exposure to the formulation, and the formulation did not kill the bacteria during a 5-minute exposure. However, acid production by *S. mutans* was inhibited for 8 hours as a result of the

5-minute exposure, as compared to the control (Ref. 438).

Study 2, carried out by Drake et al. (Ref. 439), was designed to determine the antimicrobial activity of the combination formulation. A spectrum of oral microorganisms was exposed to various dilutions of the combination formulation (1:2 and 1:128) for times varying from 5 minutes to 2 hours. MIC's varied among the species tested. Periodontal pathogens, including *P. gingivalis*, *F. mucleatum*, *E. corrodens*, and *A. actinomycetemcomitans*, were among the more susceptible of the species tested, with MICs between dilutions of 1:64 and 1:28. Streptococci tended to be less susceptible. Under this protocol, *S. mutans* was inhibited by dilutions as low as 1:32, whereas in the previous study the combination formulation appeared to be ineffective even at dilutions as low as 1:4 (Ref. 438). This apparent discrepancy with study 1 is likely due to the longer exposure time of the bacteria in study 2 (up to 2 hours). Exposures of 15 minutes at a dilution of 1:4, or 5-minutes at a dilution of 1:2, were needed to kill all *S. mutans* cells in this study. Because mouthrinses are seldom used clinically for more than 30 to 60 seconds, it is doubtful that these results reflect the antibacterial effect of the mouthrinse in actual use.

3. *Human clinical trials*. One 6-week, blinded, parallel clinical trial compared the relative efficacy of two of the three combination formulations on plaque and gingivitis in a human adult population (Ref. 438). Subjects were divided into three groups, using either a commercial toothpaste and toothbrush (control), the ''regular strength'' (single-bottle) formulation and a commercial toothpaste and toothbrush, or the orthodontic strength'' (twin-bottle formulation not containing five times the concentration of zinc chloride) and a commercial toothpaste and toothbrush. Following the baseline examination, each subject was instructed to brush twice a day and, if assigned to a mouthrinse, to use the rinse after brushing. Baseline and 6-week data included the Loe and Silness Gingival Index recorded on six surfaces per tooth, and Turesky's modification of the Quigley-Hein Plaque Index. A mean score per subject was calculated for each index. The results are in Table 16.

TABLE 16.—GINGIVAL INDEX AND PLAQUE INDEX SCORES FROM THE GROSSMAN STUDY (REF. 438)

Experimental Groups	Baseline Gingival Index	6-week Gingival Index	Baseline Plaque Index	6-week Plaque Index
Group 1 (control)	1.52	1.40	20.76	18.56
Group 2 (1-bottle)	1.48	1.32	19.91	11.73
Group 3 (2-bottle)	1.47	1.33	19.15	12.84

Although the reduction in gingival index score was statistically significant for all three groups, the clinical significance of this reduction was marginal at best. There were no statistically significant differences among the three groups. The plaque index reduction was statistically significantly better for the mouthrinse groups than for the control group. However, the control group lacked a placebo rinse to determine whether the difference in plaque reduction was due to the rinsing effect or to some of the active ingredients in the test rinses. The degree of plaque reduction for any of the groups is of questionable clinical significance, because it did not result in any meaningful reduction of the gingivitis score.

In another double-blind clinical study (Ref. 440), 119 adults were fitted with a toothshield (for either the right or left mandibular quadrant) that was designed to prevent toothbrushing from disturbing plaque accumulation. All subjects received an initial prophylaxis and were assigned to one of three experimental groups, each of which brushed their teeth (except for the shielded quadrant) once a day and used a different mouthrinse formulation twice a day for 1 minute. The final examination took place after 3 weeks, and 102 subjects completed the trial. Two rinses were variations of the two-phase system formula used in the 1-bottle and 2-bottle formulations. The third formulation was a control rinse dispensed as a two-phase system. The results show no statistically significant differences in gingival index scores or bleeding sites among the three experimental regimens, either on the shielded or nonshielded teeth.

Plaque scores (Modified Turesky Plaque Index) were higher on shielded versus nonshielded teeth. The plaque scores after 3 weeks were lower for the two test rinses compared to the control rinse for both shielded and nonshielded teeth. However, the differences in plaque scores, while statistically significant, were not clinically significant.

TABLE 17.—DATA FOR SHIELDED TEETH FROM THE BESSELAAR LABS STUDY (REF. 440)

Experimental Groups	Modified Plaque Index Baseline	Mean ± Std. Error 3-Week
Data for Shielded Teeth		
Group 1 (Test 1)	2.21 ± 0.08	2.73 ± 0.08
Group 2 (Test 2)	2.14 ± 0.09	2.61 ± 0.09
Group 3 (Control)	2.15 ± 0.09	3.03 ± 0.09
Data for Nonshielded Teeth		
Group 1 (Test 1)	1.95 ± 0.07	1.76 ± 0.07
Group 2 (Test 2)	1.88 ± 0.08	1.63 ± 0.09

TABLE 17.—DATA FOR SHIELDED TEETH FROM THE BESSELAAR LABS STUDY (REF. 440)—Continued

Experimental Groups	Modified Plaque Index Baseline	Mean ± Std. Error 3-Week
Group 3 (Control)	1.91 ± 0.07	2.24 ± 0.06

The study results indicated that the test rinses had a marginal effect, at best, on plaque reduction, because plaque scores actually increased for all groups on shielded teeth, although less so, for the experimental rinses. None of the tested rinses had any effect to prevent development of gingivitis.

Data collected in individual dental offices by dental practitioners (Ref. 437) had no protocols and lacked the basic requirements for controlled, randomized clinical trials. Therefore, these data were of questionable value.

The Subcommittee concludes that this combination of ingredients is safe, but there are insufficient data to support its effectiveness as an OTC antigingivitis/antiplaque agent.

e. *Peppermint oil and sage oil*. The Subcommittee concludes that peppermint oil and sage oil are safe, but there are insufficient data to classify the effectiveness of the combination as an OTC antigingivitis/antiplaque agent.

Peppermint oil is described as the volatile oil distilled with steam from the fresh overground parts of the flowering plant *Mentha piperita linne*, rectified by distillation and neither partially nor wholly dementholized (Refs. 441 and 442).

Sage oil is derived from the dried leaves of the plant *Salvia officinalis*, which contains the essential oil (Ref. 443). It is described as having carminative and astringent properties and is used as a flavoring agent. It is used with other volatile agents in preparations for respiratory-tract disorders, and in mouthwashes and gargles for disorders of the mouth and throat. It is also used in homeopathic medicine.

Both peppermint oil and sage oil were reviewed by the Advisory Review Panel on OTC Oral Cavity Drug Products, which classified them as inactive ingredients (47 FR 22760 at 22764).

i. *Safety*. Peppermint oil has been used as a food flavoring for many years (21 CFR 182.20). Safety studies on peppermint oil continue to the present. For example, Spindler and Madsen (Ref. 444) conducted a toxicity study in rats giving peppermint oil orally to groups of rats at dosage levels of 0, 10, 40, and 100 mg/kg body weight. Some encephalopathy and nephropathy were seen at the highest dose. The authors determined a NOAEL of 40 mg/kg body weight per day.

Immunotoxicity testing of commonly used food flavoring ingredients including peppermint oil was reported (Ref. 445). Humoral and cell-mediated immune responses in mice were evaluated. Only at very high dose levels did peppermint oil increase mortality rate and reduce survival time in the host resistance assay, but it did not significantly alter humoral immunity.

Toothpaste and mouth rinse products containing both peppermint oil and sage oil were tested on the skin of rabbits with either no or slight-to-moderate irritant effects reported. Oral toxicity in rats showed no gross post mortem change. No untoward irritation or sensation relative to the oral mucosa was reported (Ref. 446).

ii. *Effectiveness*. The Subcommittee concludes that there are insufficient data from controlled studies to permit final classification of the effectiveness of peppermint oil and sage oil as OTC active ingredients for the reduction of plaque and gingivitis.

A single-blind study (Ref. 447) showed significantly less bleeding and less plaque in 25 dental students following 1 month use of the test toothpaste and oral rinse compared to 25 students using the placebo. However, all the relatively young dental students (age 25.5 ± 2.1 years) began with relatively low initial scores.

Although several efficacy studies of a toothpaste and an oral rinse containing peppermint oil and sage oil have been conducted (Ref. 448), these studies lack various aspects of double-blind, well-controlled research.

f. *Polydimethylsiloxane and poloxamer*. The Subcommittee concludes that these ingredients are safe, but there are insufficient data available to permit final classification of the effectiveness of the combination of polydimethylsiloxane and poloxamer as an OTC antigingivitis/antiplaque agent. The active ingredient is polydimethylsiloxane (dimethicone, simethicone), a fully methylated linear siloxane polymer used for its antifoaming properties in a number of marketed ingestible products such as antacids and certain foods (21 CFR 176.200). In order to insure the emulsification of the active ingredient, poloxamer, a polymer of polyoxyethylene, is used as a nonionic surfactant.

Polydimethylsiloxane combines readily with a number of other ingredients and has been packaged into different formulations (including sprays, mouthrinses, and dentifrices) and incorporated into oral hygiene devices (such as floss and interdental stimulators) and chewing gum. The ratio of the poloxamer to the polydimethylsiloxane varies from 100:1 in rinses to 1:1 in chewing gums. Concentrations range from 0.4 to 4 percent for liquid and gel emulsions, including toothpastes, and .01 to 0.2 g per use for interdental cleansing devices coated with solid emulsion, as well as chewing gum and mints.

i. *Safety*.

1. *Toxicity in animals*. Toxicity data in animals (Ref. 449) and humans (Ref. 450) indicate that polydimethylsiloxane has minimal toxicity. The biological safety of polydimethysiloxane has been tested by subdermal, intramuscular, and subcutaneous administration at greatly exaggerated dose levels in rats for periods of up to 26 weeks and further followups of up to 2 years. Monitoring included hematological and urinary chemistry, clinical parameters, and gross and microscopic anatomy. No effect was noted on the survival, body weights, clinical chemistry, hematology, urine chemistry, organ weights, or gross and microscopic anatomical features of the test animals that could be related to the tested product (Ref. 449). Acute toxicity testing of the poloxamer indicated minimal or no side effects from exaggerated doses via ingestion and intraocular administration of the tested products (Ref. 449).

The combination of poloxamer and dimethicone, packaged as a gel, was tested for acute oral toxicity in rats and in a 20-day hamster cheek pouch application study. At a dose level of 10 g/kg of body weight no deaths were observed in the rat study. If this combination were toxic, at this dose level it would have been expected to kill one half or more of the animals. Additionally, no abnormal changes were observed in the cheek pouches after topical applications of 0.1 mL of the combination three times daily for 4 weeks.

2. *Toxicity in humans*. No human toxicity data were submitted because poloxamer and dimethicone are categorized as safe (Ref. 450). The long-term use of the ingredients in antacids,

antiflatulents, and as an additive to certain foods without any report of harmful effects indicates that this combination is safe in the dosages and formulations in current use. The estimated daily intake varies from 0.2 g or less for sprays, gels, dentifrices, rinses, or dental floss to a high of 0.4 g per breath mint or candy (Ref. 451).

ii. *Effectiveness*.

1. *Mechanisms of action*. This combination acts by reducing the surface energy of the tooth (Ref. 452). Glantz (Ref. 453) showed a rapid increase in plaque formation with increasing surface energy in an in vitro assay. By reducing the surface energy with various surfactants, the rate of dental plaque build up can be theoretically reduced, particularly in the initial stages of dental plaque formation.

2. *Results from human clinical trials*. In general, most of the human studies have shown a marginal reduction in plaque formation in the test groups, using assorted formulations, as compared to the placebo or control group. In those studies that monitored gingivitis, no detectable difference in gingivitis was observed between the test and control groups.

TABLE 18.—TYPICAL PLAQUE SCORES FROM REPRESENTATIVE STUDIES MEASURING CHANGES FROM A BASELINE WITH OR WITHOUT AN INITIAL PROPHYLAXIS (REF. 454)

Study	Groups(n)	Baseline	End	Mean Difference
Study 1986–01	Test(10)	1.83	2.04	0.21
(OTC vol. 210259)	Control(10)	1.78	2.10	0.31
Study 1986–02	Test(13)	0	1.62	T vs C[1]
(OTC vol. 210259)	Control(13)	0	1.78	0.16
Study WHOIT–1990	Test(32)	0	2.06-2.16	T vs C
(OTC vol. 210259)	Control(32)	0	2.30	0.14–0.24
Study WHD–001	Test(30)	2.75	2.73	0.02
(OTC vol. 210259)	Control(30)	2.62	2.69	0.06
Study 47–01	Test(30)	0	1.87	T vs C
(OTC vol. 210260)	Control(30)	0	2.11	0.24
(Gingival Index score)	Test(30)	0	1.47	T vs C
	Control(30)	0	1.56	0.09

[1]T vs C means Test versus Control.

The protocols differed significantly from one another, as did the formulations of the test products. Nevertheless, it was clear that the differential effect on plaque scores between test and controls, while statistically significant, was not clinically relevant. Nor was it likely that the reduction in plaque scores is responsible for any potential cosmetic benefits that might be claimed. Therefore, it is misleading to claim that this combination has a plaque inhibitory effect. Such a claim might suggest a beneficial therapeutic or at least a cosmetic effect. While the plaque claim may be technically correct, the marginal nature of the effect is unlikely to have any clinically significant benefit, either therapeutic or cosmetic.

g. *Stannous pyrophosphate and zinc citrate*. The Subcommittee concludes that this combination of ingredients is safe, but there is insufficient evidence of its effectiveness as an OTC antigingivitis/antiplaque agent. Stannous pyrophosphate has the chemical formula $Sn_2P_2O_7$ and is a free flowing, odorless white to offwhite powder (Ref. 455). The commercial form of stannous pyrophosphate is anhydrous stannous pyrophosphate. This ingredient has been used in a dentifrice based on prior demonstrated antibacterial effects, which have been ascribed to the soluble stannous ion.

Because of reported antiplaque and anticalculus effectiveness, zinc citrate was combined in a dentifrice with stannous pyrophosphate (see discussion of zinc citrate chemistry in section III.C of this document).

i. *Safety*. Based on animal studies and human use, the two ingredients used in the combination do not appear to present a risk in terms of acute toxicity, chronic toxicity, reproduction toxicity, genotoxicity, carcinogenicity, phototoxic sensitization, or oral irritation. Oral ecology studies were done to ensure that long-term use of antimicrobial agents does not result in a significant change in the balance of the normal flora. In a 21-day experimental gingivitis study by Watson, Jones, and Richie (Ref. 456) and a 6-month clinical trial by Jones et al. (Ref. 457), following use of a dentifrice containing stannous pyrophosphate (1 percent) and zinc citrate (0.5 percent), there were no significant changes in plaque flora, no increase in opportunistic organisms in saliva, and no development of resistance.

ii. *Effectiveness*. Data on the clinical effectiveness of a fluoride toothpaste containing stannous pyrophosphate (1 percent) and zinc citrate (0.5 percent) included four studies: (1) An 18-hour plaque growth inhibition test, (2) a 21-day experimental gingivitis trial, (3) a 12-week motivational brushing trial, and (4) a 6-month normal use clinical trial.

The plaque growth inhibition studies used an 18-hour protocol described by Harrap (Ref. 458) to test the effect of the combination dentifrice on plaque growth in vivo. Lloyd (Ref. 459) reported that the formulation reduced plaque significantly compared to a placebo toothpaste, showing the antimicrobial activity of the two

ingredients when formulated into a dentifrice.

A 21-day experimental gingivitis study by Saxton and Cummins (Ref. 460) enrolled 37 subjects who were brought to a state of no gingival inflammation following 4 weeks of repeated professional cleaning and oral hygiene instruction. One posterior lower segment of tooth was covered with a vacuum-formed tooth shield as described by Bosman and Powell (Ref. 461). Subjects were instructed not to brush that segment of the tooth, which was covered when the subjects cleaned the remainder of their dentition. The tooth shields also served as carriers for the daily application of the control and test toothpastes. Assessment of inflammation and bleeding was done at baseline and at 3 weeks. Mean scores were significantly lower for the test group at 3 weeks, which was interpreted as the test dentifrice being better in delaying development of gingivitis.

A 12-week motivational brushing trial by Gaare et al. (Ref. 462) included 81 adult subjects described as receiving a prophylaxis and motivation at baseline and then using the combination dentifrice at least twice daily. Plaque index and GI scores improved at 6 weeks; plaque scores continued to improve at 12 weeks; and bleeding scores were maintained at 12 weeks.

A 6-month normal use clinical study by Saxton et al. (Ref. 463) enrolled 268 subjects, with 251 completing the trial. Clinical assessments were made at baseline and at 1, 4, and 6 months. Tooth scaling and polishing were done after baseline assessments, which included plaque index by Loe (Ref. 464), modified gingival index by Lobene (Ref. 112), extrinsic stain indices by Lobene (Ref. 465), supragingival calculus by Volpe (Ref. 466), and gingival bleeding by Ainamo and Bay (Ref. 467). The results at 6 months showed no difference in mean plaque scores and no difference in mean modified gingival index scores. Gingival bleeding was statistically significantly lower for the test group ($p<0.01$) as was the mean calculus scores ($p<0.01$). Tooth staining area mean scores were statistically significantly higher ($p<0.05$) and the stain intensity mean score was also higher ($p<0.00$) for the test group. It was reported that 17 percent of the test group observed tooth staining for themselves. Tongue staining was clinically detectable in approximately 40 percent of test dentifrice subjects compared to approximately 10 percent of control dentifrice subjects (53 versus 15 subjects at 6 months).

The Subcommittee concludes that the combination of stannous pyrophosphate (1 percent) and zinc citrate (0.5 percent) in a dentifrice is safe. However, there are insufficient data to permit final classification of its effectiveness as an OTC antigingivitis/antiplaque agent.

IV. Analysis of Impacts

FDA seeks specific comment regarding any substantial or significant economic benefit or impact that this proposed rule would have on manufacturers or consumers of antigingivitis/antiplaque drug products. Comments regarding the benefit or impact of this proposed rule on such manufacturers or consumers should be accompanied by appropriate documentation. The agency will evaluate any comments and supporting data that are received and will assess the economic impact of this proposed rule in the preamble to the proposed rule.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Request for Comments

The agency is providing interested persons a period of 90 days to submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) regarding this advance notice of proposed rulemaking. Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. The agency is also providing interested persons a period of 150 days to submit comments replying to comments regarding this advance notice of proposed rulemaking. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

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

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List of Subjects in 21 CFR Part 356

Over-the-counter drugs, Antigingivitis/antiplaque drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 356 (as proposed in the **Federal Register** of May 25, 1982 (47 FR 22760), the **Federal Register** of January 27, 1988 (53 FR 2436), the **Federal Register** of September 24, 1991 (56 FR 48302), and the **Federal Register** of February 9, 1994 (59 FR 6084)) be amended as follows:

PART 356—ORAL HEALTH CARE DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

1. The authority citation for 21 CFR part 356 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 356.3 is amended by adding paragraphs (o) and (p) to read as follows:

§ 356.3 Definitions.

* * * * *

(o) *Antigingivitis drug*. A drug applied to the oral cavity to help reduce or prevent gingivitis.

(p) *Antigingivitis/antiplaque drug*. A drug applied to the oral cavity to help reduce or prevent gingivitis and dental plaque.

3. Section 356.13 is added to subpart B to read as follows:

§ 356.13 Antigingivitis active ingredients.

The active ingredient of the product consists of stannous fluoride 0.454 percent in a compatible dentifrice base.

4. Section 356.15 is added to subpart B to read as follows:

§ 356.15 Antigingivitis/antiplaque active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient:

(a) Cetylpyridinium chloride 0.045 to 0.1 percent in a mouthrinse with at least 72 to 77 percent available cetylpyridinium chloride.

(b) Eucalyptol 0.092 percent in a mouthrinse when combined in accordance with § 356.26(p).

(c) Menthol 0.042 percent in a mouthrinse when combined in accordance with § 356.26(p).

(d) Methyl salicylate 0.060 percent in a mouthrinse when combined in accordance with § 356.26(p).

(e) Thymol 0.064 percent in a mouthrinse when combined in accordance with § 356.26(p).

5. Section 356.24 is amended by redesignating the text as paragraph (a) and by adding paragraph (b) to read as follows:

§ 356.24 Package-size limitations.

* * * * *

(b) Due to the toxicity associated with fluoride active ingredients in § 355.10 of this chapter, the following package-size limitations are required for antigingivitis drug products containing stannous fluoride:

(1) *Dentifrices*. Dentifrice (toothpaste) packages shall not contain more than 276 milligrams (mg) total fluorine per package.

(2) *Exception*. Package size limitations do not apply to antigingivitis/antiplaque drug products marketed for professional office use only and labeled in accordance with § 355.60 of this chapter.

6. Section 356.26 is amended by adding paragraphs (p), (q), (r), and (s) to read as follows:

§ 356.26 Permitted combinations of active ingredients.

* * * * *

(p) The ingredients identified in § 356.15(b), (c), (d), and (e) may be combined in a hydroalcoholic vehicle containing 21.6 to 26.9 percent alcohol in a mouthrinse provided the product is labeled according to § 356.65.

(q) The antigingivitis/antiplaque active ingredient identified in § 356.15(a) or the combination of ingredients identified in § 356.26(p) may be combined with any single anticaries active ingredient identified in § 355.10 of this chapter.

(r) The antigingivitis active ingredient identified in § 356.13(a) or the antigingivitis/antiplaque active ingredient identified in § 356.15(a) or the combination of ingredients identified in § 356.26(p) may be combined with any single tooth desensitizer active ingredient identified in § 356.22.

(s) The antigingivitis/antiplaque active ingredient identified in § 356.15(a) or the combination of ingredients identified in § 356.26(p) may be combined with any single anticaries active ingredient identified in § 355.10 of this chapter and any single tooth desensitizer active ingredient identified in § 356.22.

7. Section 356.65 is added to subpart C to read as follows:

§ 356.65 Labeling of antigingivitis/antiplaque drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as ''antigingivitis'' or ''antigingivitis/antiplaque'' (optional: may include dosage form, e.g., dentifrice, toothpaste, mouthrinse).

(b) *Indications*. The labeling of the product states, under the heading ''Uses,'' one or more of the phrases

listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this part, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For all antigingivitis products*. The labeling states ''[bullet][1] helps [select one of the following: 'control,' 'reduce,' or 'prevent'] [select one or more of the following: '[bullet] gingivitis,' '[bullet] gingivitis, an early form of gum disease,' or '[bullet] bleeding gums'].''

(2) *For antigingivitis products containing stannous fluoride*. The labeling states the indication in paragraph (b)(1) of this section and/or the following: ''[bullet] helps interfere with harmful effects of plaque associated with gingivitis''.

(3) *For all antigingivitis/antiplaque products*. The labeling states ''[bullet] helps [select one of the following: 'control,' 'reduce,' 'prevent,' or 'remove'] plaque that leads to [select one or more of the following: '[bullet] gingivitis,' '[bullet] gingivitis, an early form of gum disease,' or '[bullet] bleeding gums'].''

(c) *Warnings*. The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) *For all antigingivitis and antigingivitis/antiplaque products*. (i) ''Stop use and ask a dentist[2] if [in bold type] [bullet] gingivitis, bleeding, or redness persists for more than 2 weeks [bullet] you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.''

(ii) The following warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

(A) ''Keep out of reach of children under 6 years of age.'' [highlighted in bold type]

(B) ''If more than used for [select appropriate word: 'brushing' or 'rinsing'] is accidentally swallowed, get medical help or contact a Poison Control Center right away.''

(2) [Reserved]

(d) *Directions*. The labeling of the product states, under the heading ''Directions,'' the following directions for use:

(1) *For antigingivitis dentifrice products containing 0.454 percent stannous fluoride in a paste dosage form with a theoretical total fluorine concentration of 850 to 1,150 parts per million identified in § 355.10(c)(1) of this chapter*. ''[bullet] adults and children 2 years of age and older: brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor [bullet] instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing) [bullet] supervise children as necessary until capable of using without supervision [bullet] children under 2 years of age: ask a dentist or doctor''.

(2) *For antigingivitis/antiplaque oral rinse products containing 0.045 to 0.1 percent cetylpyridinium chloride*. ''[bullet] adults and children 12 years of age and older: vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse. [bullet] children 6 years to under 12 years of age: supervise use [bullet] children under 6 years of age: do not use''.

(3) *For antigingivitis/antiplaque oral rinse products containing the combination of ingredients in § 356.26(p)*. ''[bullet] adults and children 12 years of age and older: vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse. [bullet] children 6 years to under 12 years of age: supervise use. [bullet] children under 6 years of age: do not use''.

(e) *Other information*. The labeling of the product contains the following information under the heading ''Other information'':

(1) *For antigingivitis dentifrice products containing stannous fluoride*. The labeling states ''[bullet] this product may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by a dentist.''

(2) *For antigingivitis/antiplaque oral rinse products*. The labeling states ''[bullet] this rinse is not intended to replace brushing or flossing''.

8. Section 356.66 is amended by adding paragraphs (b)(10), (c)(5), and (d)(3) to read as follows:

§ 356.66 Labeling of combination drug products.

* * * * *

(b) * * *

(10) *For permitted combinations identified in § 356.26(p)*. The labeling of the product states, under the heading ''Uses,'' one or more of the indications for antigingivitis/antiplaque active ingredients in § 356.65(b)(3), or the following: ''[bullet] helps [select one of the following: 'control,' 'inhibit,' or 'kill'] plaque bacteria that contribute to the development of [select one or more of the following: '[bullet] gingivitis,' '[bullet] gingivitis, an early form of gum disease,' or '[bullet] bleeding gums'].''

(c) * * *

(5) *For permitted combinations identified in § 356.26*. The warnings in § 356.65(c) should be used.

(d) * * *

(3) For permitted combinations identified in § 356.26. The directions in § 356.65(d) should be used.

9. Section 356.92 is added to subpart D to read as follows:

§ 356.92 Testing of antigingivitis/antiplaque drug products.

The following testing should be conducted on the product formulation, a standard formulation with effectiveness documented by clinical trials, and a negative control.

(a) *Cetylpyridinium chloride rinse*. One of the following tests should be conducted:

(1) Determine the in vitro antimicrobial activity of the product against representative plaque organisms commonly associated with gingivitis. Representative organisms include, but are not limited to, typed stains of: *Actinomyces viscosus*, *Fusobacterium nucleatum*, *Porphyromonas gingivalis*, *Prevotella intermedia*, *Bacteroides forsythus*, *Candida* species, *Streptococcus mutans*, and gram negative enteric rods. Testing to determine a product's in vitro antimicrobial activity should include minimal inhibitory concentration (MIC) assays, or 30-second kill-time studies, as appropriate.

(2) Demonstrate the availability of the active ingredient using a Disk Retention Assay (DRA).

(3) Demonstrate the biological activity of the product using an ex vivo Plaque Glycolysis and Regrowth Model (PGRM).

(b) *Combination of ingredients identified in § 356.26(p)*. One of the following tests should be conducted:

(1) Determine the in vitro antimicrobial activity of the product using 30-second kill-time studies with both standard laboratory strains and

[1]See § 201.66(b)(4) of this chapter for definition of bullet symbol.

[2]For these products, the word ''dentist'' should be substituted for ''doctor'' in the heading ''Stop use and ask a doctor if'' required by § 201.66(c)(5)(vii) of this chapter.

wild-type organisms obtained from saliva sampling. Representative organisms include, but are not limited to, typed stains of: *Actinomyces viscosus*, *Fusobacterium nucleatum*, *Porphyromonas gingivalis*, *Prevotella intermedia*, *Bacteroides forsythus*, *Candida* species, *Streptococcus mutans*, and gram negative enteric rods. Kill-time testing should be conducted using an exposure time of 30 seconds in the presence of exogenous protein. An initial inoculum of 1 percent transmission should be used.

(2) Demonstrate the in vivo activity of the product in a short-term experimental gingivitis study of at least 2 weeks duration. Formulation comparability in this test is established if the new mouthrinse formulation satisfies the ''at least as good as'' statistical criteria for both plaque and gingivitis with respect to the clinically tested standard, or another generally accepted statistical test of clinical comparability. The criterion for study validation is statistically significant differences in plaque and gingivitis between the clinically tested standard and the negative control.

(c) *Stannous fluoride dentifrice*.

(1) In addition to tests required by § 355.70 of this chapter, testing should include an in vitro determination of the antimicrobial activity against representative plaque organisms commonly associated with gingivitis. Representative organisms include, but are not limited to, typed stains of: *Actinomyces viscosus*, *Fusobacterium nucleatum*, *Porphyromonas gingivalis*, *Prevotella intermedia*, *Bacteroides forsythus*, *Candida* species, *Streptococcus mutans*, and gram negative enteric rods. Testing to determine a product's in vitro antimicrobial activity should include MIC assays, 30-second kill-time studies, or plaque biofilm assays, as appropriate.

(2) Demonstrate the biological activity of the product ex vivo using PGRM.

(d) *Test modifications*. The formulation or mode of administration of certain products may require modification of the testing procedures in this section. In addition, alternative assay methods (including automated procedures) employing the same basic chemistry or microbiology as the methods described in this section may be used. Any proposed modification or alternative assay method shall be submitted as a petition in accordance with § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative assay method provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in part 20 of this chapter.

Dated: May 12, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12783 Filed 5–28–03; 8:45 am]

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Part IV

Department of Labor

Civil Rights Center; Enforcement of Title VI of the Civil Rights Act of 1964; Policy Guidance to Federal Financial Assistance Recipients Regarding the Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons; Notice

DEPARTMENT OF LABOR

Office of the Secretary

Civil Rights Center; Enforcement of Title VI of the Civil Rights Act of 1964; Policy Guidance to Federal Financial Assistance Recipients Regarding the Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of policy guidance with request for comment.

SUMMARY: The Department of Labor (DOL) publishes Revised Guidance to Federal Financial Assistance Recipients Regarding the Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (Revised DOL Recipient LEP Guidance). This Revised DOL Recipient LEP Guidance is issued pursuant to Executive Order 13166.

DATES: This Guidance is effective immediately. Comments must be submitted on or before June 30, 2003. DOL will review all comments and will determine what modifications to the Guidance, if any, are necessary. This Guidance supplants existing guidance on the same subject originally published at 66 FR 4596 (January 17, 2001).

ADDRESSES: Interested persons should submit written comments to Ms. Annabelle T. Lockhart, Director, Civil Rights Center, U.S. Department of Labor, 200 Constitution Ave., NW., Room N–4123, Washington, DC 20210. Commenters wishing acknowledgment of their comments must submit them by certified mail, return receipt requested. Please be advised that mail delivery to federal buildings in the Washington, DC metropolitan area may experience delays due to concerns about anthrax contamination. Comments may also be transmitted by facsimile to (202) 693–6505 or by e-mail to *civilrightscenter@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Annabelle Lockhart or Naomi Barry-Pérez at the Civil Rights Center, U.S. Department of Labor, 200 Constitution Ave., NW., Room N–4123, Washington, DC 20210. Telephone: 202–693–6500; TTY: 202–693–6515. Arrangements to receive the Guidance in an alternative format may be made by contacting the named individuals.

SUPPLEMENTARY INFORMATION: Under DOL regulations implementing Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, *et seq.* (Title VI), recipients of federal financial assistance have the responsibility to ensure meaningful access to their programs and activities by persons with limited English proficiency (LEP). See 29 CFR part 31. Executive Order 13166, reprinted at 65 FR 50121 (August 16, 2000), directs each federal agency that extends assistance subject to the requirements of Title VI to publish guidance for its respective recipients clarifying that obligation. Executive Order 13166 further directs that all such guidance documents be consistent with the compliance standards and framework detailed in the Department of Justice (DOJ) Policy Guidance entitled ''Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons with Limited English Proficiency.'' See 65 FR 50123 (August 16, 2000).

On January 17, 2001, DOL published Guidance on how Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000d, *et seq.,* and its implementing regulations apply to recipients of DOL financial assistance in their contact with persons who are limited English proficient (''LEP Guidance''). See 66 FR 4596. The LEP Guidance also addressed the responsibilities of recipients under Section 188 of the Workforce Investment Act, Public Law 105–220, 29 U.S.C. 2938, and its implementing regulations, which adopt the same prohibition against national origin discrimination that is found in Title VI. DOL received extensive comments following the January 17, 2001 publication of the LEP Guidance.

On March 14, 2002, the Office of Management and Budget (OMB) issued a Report to Congress titled ''Assessment of the Total Benefits and Costs of Implementing Executive Order No. 13166: Improving Access to Services for Persons with Limited English Proficiency.'' Among other things, the Report recommended the adoption of uniform guidance across all Federal agencies, with flexibility to permit tailoring to each agency's specific recipients. Consistent with this OMB recommendation, DOJ published LEP Guidance for DOJ recipients, which was drafted and organized to also function as a model for similar guidance documents by other Federal grant agencies. See 67 FR 41455 (June 18, 2002).

This revised DOL Guidance reflects consideration of comments received and the additional guidance of DOJ. Following DOJ's direction, we will again accept public comment and will revise and republish, as appropriate. Because DOJ has indicated that this Guidance must adhere to the federal-wide compliance standards and framework detailed in the model DOJ LEP Guidance issued on June 18, 2002, DOL specifically solicits comments on the nature, scope and appropriateness of the DOL-specific examples set out in this guidance explaining and/or highlighting how those consistent federal-wide compliance standards are applicable to recipients of federal financial assistance through DOL.

The model DOJ LEP guidance includes a section regarding ''safe harbors'' for written translations of vital material. That section states:

''Safe Harbor. Many recipients would like to ensure with greater certainty that they comply with their obligations to provide written translations in languages other than English. Paragraphs (a) and (b) outline the circumstances that can provide a ''safe harbor'' for recipients regarding the requirements for translation of written materials. A ''safe harbor'' means that if a recipient provides written translations under these circumstances, such action will be considered strong evidence of compliance with the recipient's written-translation obligations.

The failure to provide written translations under the circumstances outlined in paragraphs (a) and (b) does not mean there is non-compliance. Rather, they provide a common starting point for recipients to consider whether and at what point the importance of the service, benefit, or activity involved; the nature of the information sought; and the number or proportion of LEP persons served call for written translations of commonly-used forms into frequently-encountered languages other than English. Thus, these paragraphs merely provide a guide for recipients that would like greater certainty of compliance than can be provided by a fact-intensive, four-factor analysis.

Example: Even if the safe harbors are not used, if written translation of a certain document(s) would be so burdensome as to defeat the legitimate objectives of its program, the translation of the written materials is not necessary. Other ways of providing meaningful access, such as effective oral interpretation of certain vital documents, might be acceptable under such circumstances.

Safe Harbor. The following actions will be considered strong evidence of compliance with the recipient's written-translation obligations:

(a) The DOJ recipient provides written translations of vital documents for each eligible LEP language group that constitutes five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be affected or encountered. Translation

of other documents, if needed, can be provided orally; or

(b) If there are fewer than 50 persons in a language group that reaches the five percent trigger in (a), the recipient does not translate vital written materials but provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of those written materials, free of cost.

These safe harbor provisions apply to the translation of written documents only. They do not affect the requirement to provide meaningful access to LEP individuals through competent oral interpreters where oral language services are needed and are reasonable.

DOL has not included a similar safe harbor provision for translations in this revised Guidance. The absence of such language is not intended to detract from or otherwise minimize the underlying obligation to ensure that LEP persons can access all vital documents. DOL encourages comments which focus on the applicability of the above safe harbor to DOL recipients, suggestions of thresholds that may better reflect DOL's universe of program customers and recipients' responsibilities, the possible advantages or disadvantages of including language similar to the model DOJ Guidance, as well as any suggestions that would ensure the consistency that OMB has recommended while at the same time ensuring that the Guidance is appropriate for the types of recipients funded by DOL.

It has been determined that this revised Guidance does not constitute a regulation subject to the rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 553, and is not subject to Executive Order 12866 (Regulatory Review and Planning, September 30, 1993).

Signed at Washington, DC this 19th of May 2003.

Elaine L. Chao,

Secretary of Labor.

I. Introduction

Most individuals living in the United States read, write, speak and understand English. There are many individuals, however, for whom English is not their primary language. For instance, according to the 2000 census, over 26 million individuals speak Spanish and almost seven million individuals speak an Asian or Pacific Island language at home. If these individuals have a limited ability to read, write, speak, or understand English, they are limited English proficient, or ''LEP.'' While detailed data has not yet been released, the 2000 census estimates that over 6.6 million Spanish speakers (representing 3.28 percent of U.S. residents over the age of 18) do not speak English ''well or at all.'' Over 1.2 million people (over the age of 18) who speak other ''Indo-European'' languages cannot speak English ''well or at all.'' Over 1.4 million Asian or Pacific Islanders (over the age of 18) speak English ''not well'' or ''not at all.'' In total, more than 10.5 million people claim to speak little or no English, demonstrating an increase of approximately four million since 1990.

Language for LEP individuals can be a barrier to accessing important benefits or services, understanding and exercising important rights, complying with applicable responsibilities, or understanding other information provided by federally assisted programs and activities. The federal government provides financial assistance to an array of services that can be made accessible to otherwise eligible LEP persons. The federal government is committed to improving the accessibility of these programs and activities to eligible LEP persons, a goal that reinforces its equally important commitment to promoting programs and activities designed to help individuals learn English. Recipients should not overlook the long-term positive impacts of incorporating or offering English as a Second Language (ESL) programs in parallel with language assistance services. ESL courses can serve as an important adjunct to a proper LEP plan. However, the fact that ESL classes are made available does not obviate the statutory and regulatory requirement to provide meaningful access for those who are not yet English proficient. Recipients of federal financial assistance have an obligation to reduce language barriers that can preclude meaningful access by LEP persons to important government services.[1]

In certain circumstances, failure to ensure that LEP persons can effectively participate in or benefit from federally assisted programs and activities may violate the prohibition under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, Title VI regulations, and Section 188 of the Workforce Investment Act (WIA) against national origin discrimination. The purpose of this Guidance is to assist recipients in fulfilling their responsibilities to provide meaningful access to LEP persons under existing law. This Guidance clarifies existing legal requirements for LEP persons by providing a description of the factors recipients should consider in fulfilling their responsibilities to LEP persons.[2] These are the same criteria DOL will use in evaluating whether recipients are in compliance with Title VI and its implementing regulations and Section 188 of WIA.

The Department of Justice (DOJ) has a unique role under Executive Order 13166. The Order charges DOJ with responsibility for providing guidance to other federal agencies on how to serve LEP individuals and for ensuring consistency among the agency-specific guidance documents. Consistency among departments of the federal government is particularly important. Inconsistency or contradictory guidance could confuse recipients of federal funds and needlessly increase costs without rendering the meaningful access for LEP persons that this Guidance and other federal agency guidance documents are designed to address. As with most government initiatives, this requires balancing several principles. While this Guidance discusses that balance in some detail, it is important to note the basic principles behind that balance. First, we must ensure that federally assisted programs aimed at the American public do not leave some behind simply because they face challenges communicating in English. This is of particular importance because, in many cases, LEP individuals form a substantial portion of those encountered in federally assisted programs. Second, we must achieve this goal while finding constructive methods to reduce the costs of LEP requirements on small businesses, small local governments, or small non-profits that receive federal financial assistance.

There are many productive steps that the Federal government, either collectively or as individual grant agencies, can take to help recipients

[1] DOL recognizes that many recipients had language assistance services in place to provide LEP individuals meaningful access to programs and activities prior to the issuance of Executive Order 13166. This Guidance provides a uniform framework for recipients to integrate, formalize, and assess the continued vitality of existing and possibly additional reasonable efforts based on the nature of the programs or activities, the current needs of the LEP populations encountered, and prior experience in providing language services in the communities served.

[2] This Guidance is not a regulation but rather a guide. Accordingly, the examples provided are illustrative and should not be construed as requirements. Title VI and its implementing regulations and Section 188 of WIA require that recipients take reasonable steps to ensure meaningful access by LEP persons. This Guidance provides an analytical framework that recipients may use to determine how best to comply with statutory and regulatory obligations to provide meaningful access to the benefits, services, information, and other important portions of their programs and activities for individuals who are limited English proficient.

reduce the costs of language services without sacrificing meaningful access for LEP persons. Without these steps, certain smaller grantees may well choose not to participate in federally assisted programs, threatening the critical functions that the programs strive to provide. To that end, DOL will continue to provide assistance and guidance in this important area and will work with recipients of DOL financial assistance, including state and local workforce agencies, advocacy groups, and LEP persons, to identify and share model plans, examples of best practices, and cost-saving approaches. Moreover, DOL intends to explore how language assistance measures, resources and cost-containment approaches developed with respect to its own federally conducted programs and activities can be effectively shared or otherwise made available to recipients, particularly small businesses, small local governments, and small non-profits. An interagency working group on LEP has developed a website, *http://www.lep.gov,* to assist in disseminating this information to recipients, federal agencies, and the communities being served.

Some have interpreted the case of *Alexander* v. *Sandoval,* 532 U.S. 275 (2001), as impliedly striking down the regulations promulgated under Title VI that form the basis for the part of Executive Order 13166 that applies to federally assisted programs and activities. DOJ has taken the position that this is not the case. Accordingly, DOL will strive to ensure that federally assisted programs and activities work in a way that is effective for all eligible beneficiaries, including those with limited English proficiency.

II. Legal Authority

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, provides that no person shall ''on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance.'' Section 602 authorizes and directs Federal agencies that are empowered to extend Federal financial assistance to any program or activity ''to effectuate the provisions of [section 601] * * * by issuing rules, regulations, or orders of general applicability.'' 42 U.S.C. 2000d–1.

Department of Labor regulations promulgated pursuant to section 602 forbid recipients from ''utiliz[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respects individuals of a particular race, color, or national origin.'' 29 CFR 31.3(b)(2).

The Supreme Court, in *Lau* v. *Nichols,* 414 U.S. 563 (1974), interpreted regulations promulgated by the former Department of Health, Education, and Welfare, including a regulation similar to that of DOL, 45 CFR 80.3(b)(2), to hold that Title VI prohibits conduct that has a disproportionate effect on LEP persons because such conduct constitutes national origin discrimination. In *Lau,* a San Francisco school district that had a significant number of non-English speaking students of Chinese origin was required to take reasonable steps to provide the LEP students with a meaningful opportunity to participate in federally funded educational programs.

In the DOL context, Section 188 of the Workforce Investment Act (WIA) provides that no individual shall be excluded from participation in, denied the benefits of, be subjected to discrimination under, or denied employment in the administration of or in connection with, any such program or activity because of race, color, religion, sex (except as otherwise permitted under Title IX of the Education Amendments of 1972), national origin, age, political affiliation or belief, status as a qualified individual with disabilities or specified noncitizenship statuses (*e.g.,* lawfully admitted resident aliens).

The regulations implementing the nondiscrimination and equal opportunity provisions of Section 188 specifically address national origin discrimination and language access. Where ''a significant number or proportion of the population eligible to be served, or likely to be directly affected, by a WIA Title I-assisted program or activity may need services or information in a language other than English in order to be effectively informed about, or able to participate in, the program or activity,'' the Section 188 regulations require recipients ''to take reasonable steps to provide services and information in appropriate languages.'' 29 CFR 37.35(a). Even where there is not a ''significant'' number or proportion of LEP persons in the community serviced by the recipient, recipients nonetheless are required to ''make reasonable efforts to meet the particularized language needs of limited-English speaking individuals who seek services or information from the recipient.'' 29 CFR 37.35(b). This means that, for instance, when the LEP population in the community serviced by a recipient does not comprise a ''significant'' number or proportion, recipients should still balance the four factors described herein to determine what steps are reasonable to meet the particularized language needs of those seeking services or information.

The regulations implementing Section 188 require the Governor of every state recipient of WIA–Title I financial assistance to establish and adhere to a Methods of Administration (''MOA''). Further, the regulations require that MOAs include a description of how the state programs and recipients have satisfied the specified requirements of the Section 188 implementing regulations, including the obligation to provide services and information in appropriate languages under the circumstances outlined in 29 CFR 37.35. Although the regulatory language differs, the obligations of recipients to provide accessibility by LEP persons to DOL financially assisted programs and activities are the same under Title VI and Section 188.

On August 11, 2000, Executive Order 13166 was issued. ''Improving Access to Services for Persons with Limited English Proficiency,'' 65 FR 50121 (August 16, 2000). Under that Order, every federal agency that provides financial assistance to non-federal entities must publish guidance on how their recipients can provide meaningful access to LEP persons and thus comply with the Title VI regulations forbidding funding recipients from ''restrict[ing] an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program'' or from ''utiliz[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respects individuals of a particular race, color, or national origin.''

On that same day, DOJ issued a general guidance document addressed to ''Executive Agency Civil Rights Officers'' setting forth broad principles for agencies to apply in developing guidance documents for recipients pursuant to the Executive Order. ''Enforcement of Title VI of the Civil Rights Act of 1964 National Origin Discrimination Against Persons With Limited English Proficiency,'' 65 FR 50123 (August 16, 2000) (''DOJ LEP Guidance'').

Subsequently, federal agencies raised questions regarding the requirements of the Executive Order, especially in light of the Supreme Court's decision in *Alexander* v. *Sandoval,* 532 U.S. 275 (2001). On October 26, 2001, Ralph F. Boyd, Jr., Assistant Attorney General for DOJ's Civil Rights Division, issued a memorandum for ''Heads of Departments and Agencies, General Counsels and Civil Rights Directors,'' which clarified and reaffirmed the DOJ LEP Guidance in light of *Sandoval.*[3] The Assistant Attorney General stated that because *Sandoval* did not invalidate any Title VI regulations that proscribe conduct that has a disparate impact on covered groups—the type of regulations that form the legal basis for the part of Executive Order 13166 that applies to federally assisted programs and activities—the Executive Order remains in force.

Pursuant to Executive Order 13166, DOL developed its own guidance document for recipients, which was initially issued on January 17, 2001. ''Guidance on Improving Access to Services for Persons with Limited English Proficiency,'' 66 FR 4596 (January 17, 2001) (DOL LEP Guidance). This Proposed Revised Guidance is thus published pursuant to Executive Order 13166 in light of the Assistant Attorney General Boyd's October 26, 2001 clarifying memorandum.

III. Who Is Covered?

Department of Labor regulations, 29 CFR part 31, require all recipients of federal financial assistance from DOL to provide meaningful access to LEP persons.[4] Federal financial assistance includes grants, training, use of equipment, donations of surplus property, and other assistance. Recipients of DOL assistance include, for example:

- State-level agencies that administer, or are financed in whole or in part with, WIA Title I funds;
- State Workforce Agencies;
- State and local Workforce Investment Boards;
- Local workforce investment areas (''local areas'') grant recipients;
- One-Stop Career Center operators;
- Service providers, including eligible training providers and youth service providers;
- On-the-Job Training (OJT) employers;
- Job Corps contractors and center operators;
- Job Corps national training contractors;
- Outreach and admissions agencies, including Job Corps contractors that perform these functions; and
- Other national program recipients.

Subrecipients likewise are covered when federal funds are passed through from one recipient to a subrecipient. This Guidance does not create any new requirements for community colleges and other educational institutions that receive federal financial assistance under the Higher Education Act as these institutions must already comply with Title VI requirements.

Pursuant to the Civil Rights Restoration Act of 1987 (CRRA), coverage extends to a recipient's entire program or activity, *i.e.,* to all parts of a recipient's operations. This is true even if only one part of the recipient receives the federal assistance.[5]

Example: DOL provides assistance to a state department of labor to support the development of the state's One-Stop Career System. While the funds may be administered by one agency within the state department, Title VI applies to all of the operations of the entire state department of labor—not just the One-Stop Career delivery system.[6]

Finally, some recipients operate in localities in which English has been declared the official language. Nonetheless, these recipients continue to be subject to federal non-discrimination requirements, including those applicable to the provision of federally assisted services to persons with limited English proficiency.

IV. Who Is a Limited English Proficient Individual?

Individuals who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English can be limited English proficient, or ''LEP,'' and entitled to language assistance with respect to a particular type of service, benefit, or encounter.

Examples of populations likely to include LEP persons who are encountered and/or served by DOL recipients and should be considered when planning language services include, but are not limited to:

- Unemployed and/or dislocated individuals seeking unemployment insurance (UI), job search and/or job training services.
- Workers, such as those doing construction or working in mines, who receive training from Occupational Safety and Health or Mine Safety and Health training providers.
- Youth looking for summer employment, academic and career exploration or vocational training and employment opportunities, such as participation in Job Corps, and their parents or family members.
- Migrant and seasonal agricultural workers seeking placement and/or information on protections afforded to them in this work.
- Workers seeking information or enforcement from a recipient regarding wage and hour and safety and health laws.

V. How Does a Recipient Determine the Extent of Its Obligation To Provide LEP Services?

Recipients are required to take reasonable steps to ensure meaningful access to their programs and activities by LEP persons. While designed to be a flexible and fact-dependent standard, the starting point is an individualized

[3] The DOJ memorandum noted that some commentators have interpreted *Sandoval* as impliedly striking down the disparate-impact regulations promulgated under Title VI that form the basis for the part of Executive Order 13166 that applies to federally assisted programs and activities. *See, e.g., Sandoval,* 532 U.S. at 286, 286 n.6 (''[W]e assume for purposes of this decision that section 602 confers the authority to promulgate disparate-impact regulations; * * * We cannot help observing, however, how strange it is to say that disparate-impact regulations are 'inspired by, at the service of, and inseparably intertwined with' Sec. 601* * * when Sec. 601 permits the very behavior that the regulations forbid.''). The memorandum, however, made clear that DOJ disagreed with the commentators' interpretation. *Sandoval* holds principally that there is no private right of action to enforce Title VI disparate-impact regulations. It did not address the validity of those regulations or Executive Order 13166 or otherwise limit the authority and responsibility of federal grant agencies to enforce their own implementing regulations.

[4] Pursuant to Executive Order 13166, the meaningful access requirement of the Title VI regulations and the four-factor analysis set forth in the DOJ LEP Guidance are to additionally apply to the programs and activities of federal agencies, including the Department of Labor.

[5] However, if a federal agency were to decide to terminate federal funds based on noncompliance with Title VI or its regulations, only funds directed to the particular program or activity that is out of compliance would be terminated. 42 U.S.C. 2000d–1.

[6] The nondiscrimination and equal opportunity provisions of WIA and its implementing regulations apply to programs and activities that are part of the One-Stop Career System and that are operated by the One-Stop Career System partners listed in section 121(b) of WIA (29 U.S.C. 2841(b)), to the extent that the programs and activities are being conducted as part of the One-Stop Career System. When a One-Stop Career System partner receives federal financial assistance from an Executive agency other than DOL, such as the Department of Education, Health and Human Services, Agriculture or Housing and Urban Development, the grant-making agency enforces the recipient's Title VI obligation. Therefore, when a One-Stop Career System partner receives federal financial assistance from an agency other than DOL, the partner should follow the LEP guidance issued by that agency, to the extent that such guidance exists. If LEP guidance has not been issued by the grant-making agency, or if that guidance does not address the activities of the One-Stop Career partner, the One-Stop Career partner should follow this Guidance until such time as the grant-making agency issues LEP guidance.

assessment that balances the following four factors: (1) The number or proportion of LEP persons served or encountered in the eligible service population; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program, activity, or service provided by the recipient; and (4) the resources available to the recipient and costs. As indicated above, the intent of this Guidance is to suggest a balance that ensures meaningful access by LEP persons to critical services while not imposing undue burdens on small businesses, small local governments, or small non-profits.

After applying the above four-factor analysis, a recipient may conclude that different language assistance measures are sufficient for the different types of programs or activities in which it engages. For instance, some of a recipient's activities will be more important than others and/or have greater impact on or contact with LEP persons, and thus may require more in the way of language assistance. The flexibility that recipients have in addressing the needs of the LEP populations they serve does not diminish, and should not be used to minimize, the obligation that those needs be addressed. DOL recipients should apply the four factors to the various kinds of contacts that they have with the public to assess language needs and decide what reasonable steps should be taken to ensure meaningful access for LEP persons.

(1) The Number or Proportion of LEP Persons Served or Encountered in the Eligible Service Population

One factor in determining what language services recipients should provide is the number or proportion of LEP persons from a particular language group served or encountered in the eligible service population. The greater the number or proportion of these LEP persons, the more likely language services are needed. Ordinarily, persons ''eligible to be served, or likely to be directly affected, by'' a recipient's program or activity, 29 CFR 37.35(a), are those who are served or encountered in the eligible service population. This population will be program-specific, and includes persons who are in the geographic area that has been approved by a federal grant agency as the recipient's service area. However, where, for instance, a recipient serves a large LEP population, the appropriate service area is most likely determined by considering local service areas and not the entire population served by the recipient. This, for example, could occur in a local workforce investment area (local area) that manages more than a single One-Stop Career Center. Instead of being guided by a population survey for the local area, each One-Stop Career Center may wish to assess its local service population.

We suggest that states operating statewide programs, such as the Unemployment Insurance program or Workforce Investment Act programs, assess statewide language groups to identify potentially significant LEP populations, and ensure that local offices conduct similar surveys of their local service populations. Small entities, such as Vermont, Delaware, and the District of Columbia, that operate only a single local workforce investment area, should assess their overall populations with an awareness of any ''pockets'' of LEP persons that may exist in certain areas (*e.g.*, the Chinatown or Adams Morgan (largely Spanish-speaking) areas of Washington, DC). Where no service area has previously been approved, the relevant service area may be that which is approved by state or local authorities or designated by the recipient itself, provided that these designations do not themselves discriminatorily exclude certain populations. For most workforce investment services, the target audience is defined in geographic rather than programmatic terms. However, some services may be targeted to reach a particular audience (*e.g.*, out-of-school youth or migrant/seasonal farmworkers). The attached Appendix provides examples to assist in determining the eligible service population. When considering the number or proportion of LEP individuals in a service area, recipients should consider LEP parent(s) when their English-proficient or LEP minor children and dependents encounter the workforce system, including youth employment and training programs and Job Corps.

In assessing the number or proportion of LEP persons eligible to be served or likely to be encountered, recipients should first examine their prior experiences with LEP encounters and determine the breadth and scope of language services that have been needed. In conducting this analysis, it is important to include language minority populations that are eligible for programs or activities but may have been underserved because of existing language barriers. Other data should be consulted to refine or validate a recipient's prior experience, including the latest census data for the area served, data from school systems and from community organizations, and data from state and local governments.[7] Community agencies, school systems, faith-based organizations, legal aid entities, and others can often assist in identifying populations for whom outreach is needed and who would benefit from recipients' programs and activities where language services are provided.

(2) The Frequency With Which LEP Individuals Come in Contact With the Program

Recipients should assess, as accurately as possible, the frequency with which they have or should have contact with LEP individuals from potential language groups seeking assistance. The more frequent the contact with a particular language group, the more likely that enhanced language services in that language are needed. The steps that are reasonable for a recipient that serves a LEP person on a one-time basis will be very different than those expected from a recipient that serves LEP persons daily. It is also advisable to consider the frequency of different types of language contacts. For example, frequent contacts with Spanish-speaking people who are LEP may require certain assistance in Spanish. Less frequent contact with different language groups may suggest a different and less intensified solution. If a LEP individual accesses a program or service on a daily basis, a recipient has greater duties than if the same individual's program or activity contact is unpredictable or infrequent. But even recipients that serve LEP persons on an unpredictable or infrequent basis should use this balancing analysis to determine what to do if a LEP individual seeks services under the program in question. This plan need not be intricate. It may be as simple as being prepared to use one of the commercially-available telephonic interpretation services to obtain immediate interpreter services. In applying this standard, recipients should take care to consider whether appropriate outreach to LEP persons could increase the frequency of contact with LEP language groups and therefore

[7] The focus of the analysis is on lack of English proficiency, not the ability to speak more than one language. Note that demographic data may indicate the most frequently spoken languages other than English as well as the percentage of people who speak other languages and who speak or understand English less than well. Some of the most commonly spoken languages other than English may be spoken by people who are also overwhelmingly proficient in English. Thus, they may not be the languages spoken most frequently by limited English proficient individuals. When using demographic data, it is important to focus on the languages spoken by those who are not proficient in English.

also increase the demand for language assistance from these LEP populations.

(3) The Nature and Importance of the Program, Activity, or Service Provided by the Recipient

The more important the activity, information, service, or program, or the greater the possible consequences of the contact to LEP individuals, the more likely language services are needed. For example, the requirements for filing a claim for Unemployment Insurance or Trade Adjustment Assistance or safety and health information in the context of Occupational Safety and Health or Mine Safety and Health training programs must be effectively communicated. A recipient needs to determine whether denial or delay of access to services or information could have serious or even life-threatening implications for a LEP individual. Decisions by a federal, state, or local entity to make an activity compulsory, such as job training and/or job search certification in the Unemployment Insurance program, can also serve as strong evidence of the program's importance.

Title VI does not require recipients to remove language barriers when English is an essential aspect of the program (such as providing civil service examinations in English when the job requires a person to communicate in English, *see Frontera* v. *Sindell*, 522 F.2d 1215 (6th Cir. 1975)), or when there is another non-pretextual ''substantial legitimate justification for the challenged practice'' and there is no comparably effective alternative practice with less discriminatory affects. *Elston* v. *Talladega County Bd. of Educ.*, 997 F.2d 1394, 1407 (11th Cir. 1993); *New York City Environmental Alliance* v. *Giuliani*, 214 F.3d 65, 72 (2nd Cir. 2000) (plaintiffs failed to show less discriminatory options available to accomplish defendant city's legitimate goal of building new housing and fostering urban renewal). However, DOL recipients are providing a service to assist individuals in employment, and should consider that LEP individuals can be learning English and another skill at the same time.[8] For example, a recipient may not need to make accessible certain health care practitioner courses to LEP persons if the ability to be fully proficient in English is a legitimate requirement of such training and the recipient has made a legitimate determination that a LEP person would not be eligible to work in the field in the local job market and at the level for which the training is targeted. However, in order for such determinations to be legitimate, recipients should conduct an objective analysis and not rely on stereotypes or anecdotal evidence regarding level of English proficiency required for such employment, and should consider the impact that participation in English-as-a-Second-Language courses may have on the ability of the LEP person to utilize the training.

(4) The Resources Available to the Recipient and Costs

A recipient's level of resources and the costs that would be imposed on it may have an impact on the nature of the steps it should take in providing language services. Smaller recipients with more limited budgets are not expected to provide the same level of language services as are larger recipients with larger budgets. In addition, ''reasonable steps'' may cease to be reasonable when the costs imposed substantially exceed the benefits. DOL has determined that costs associated with providing meaningful access to LEP persons are considered allowable program costs. This is consistent with the discussion of administrative and program costs under Title I of WIA found in 20 CFR 667.220.

Resource and cost issues, however, can often be reduced by technological advances; the sharing of language assistance materials and services among and between recipients, advocacy groups, and federal grant agencies; and reasonable business practices. Where appropriate, training bilingual staff to act as interpreters and translators, information sharing through industry groups, telephonic and video conferencing interpretation services, pooling resources and standardizing documents to reduce translation needs, using qualified translators and interpreters to ensure that documents need not be ''fixed'' later and that inaccurate interpretations do not cause delay or other costs, centralizing interpreter and translator services to achieve economies of scale; or, the formalized use of qualified community volunteers, for example, may help reduce costs.[9] Recipients should carefully explore the most cost-effective means of delivering competent and accurate language services before limiting services due to resource concerns. Large entities and those entities serving a significant number or proportion of LEP persons should ensure that their resource limitations are well-substantiated before using this factor as a reason to limit language assistance. Such recipients may find it useful to be able to articulate, through documentation or in some other reasonable manner, the process used for determining that language services would be limited based on resources or costs.

This four-factor analysis necessarily implicates the ''mix'' of LEP services required. Recipients have two main ways to provide language services: Oral interpretation either in person or via a telephone interpretation service (hereinafter ''interpretation'') and written translation (hereinafter ''translation''). Oral interpretation can range from on-site interpreters for critical services provided to a high volume of LEP persons to access through commercially-available telephonic interpretation services. Written translation, likewise, can range from translation of an entire document to translation of a short description of the document. In some cases, language services should be made available on an expedited basis while in others the LEP individual may be referred to another office of the recipient for language assistance.

The correct mix should be based on what is both necessary and reasonable in light of the four-factor analysis. For instance, a One-Stop Career Center in a largely Hispanic neighborhood may need immediate oral interpreters available and should give serious consideration to hiring some bilingual staff. (Of course, many recipients have already made such arrangements.) There may be circumstances where the importance and nature of the activity and number or proportion and frequency of contact with LEP persons may be low and the costs and resources needed to provide language services may be high.

VI. Selecting Language Assistance Services

Regardless of the type of language service provided, for both oral and written language services, quality and accuracy of the language service is critical in order to avoid serious consequences to the LEP person and to the recipient.

A. Oral Language Services (Interpretation)

Interpretation is the act of listening to something in one language (source language) and orally translating it into another language (target language).

[8] Consistent with footnote 2, *supra*, a consideration of this factor should not be construed as requiring DOL recipients to create new programs under this Guidance.

[9] Small recipients with limited resources may find that entering into a bulk telephonic interpretation service contract will prove cost effective.

Where interpretation is needed and is reasonable, recipients should consider some or all of the options discussed below for providing competent interpreters in a timely manner.

Competence of Interpreters. When providing oral assistance, recipients should ensure competency of the language service providers, no matter which of the following strategies are used. Competency requires more than self-identification as bilingual. Some bilingual staff and community volunteers, for instance, may be able to communicate effectively in a language other than English when communicating information directly in that language, but may not be competent to interpret in and out of English. Likewise, they may not be able to do written translations.

Competency to interpret, however, does not necessarily mean formal certification as an interpreter, although certification is helpful. When using interpreters, recipients should ensure that interpreters:

- Demonstrate proficiency and ability to communicate information accurately in both English and in the other language and be able to identify and employ the appropriate mode of interpreting (*e.g.,* consecutive, simultaneous, summarization, or sight translation); [10]
- Have knowledge in both languages of any specialized terms or concepts peculiar to the recipient's program or activity and of any particularized vocabulary and phraseology used by the LEP person; [11]
- Understand and follow confidentiality and impartiality rules to the same extent the recipient employee for whom they are interpreting and/or to the extent their position requires; and
- Understand and adhere to their role as interpreters without deviating into a role as counselor, legal advisor, or other roles (particularly in administrative hearings, such as UI appeals hearings).

Some recipients, such as those that conduct administrative hearings, may have additional self-imposed requirements for interpreters. Where individual rights depend on precise, complete, and accurate interpretation or translations, particularly in the context of administrative hearings, the use of certified interpreters is strongly encouraged.[12] Where such proceedings are lengthy, the interpreter will likely need breaks and team interpreting may be appropriate to ensure accuracy and to prevent errors caused by mental fatigue of interpreters.

The quality and accuracy of language services is part of the appropriate analysis of LEP services required. For example, the quality and accuracy of language services in a UI appeals hearing or safety and health training, for example, must be extraordinarily high, while the quality and accuracy of language services in providing optional career planning tools, such as ''tests'' that evaluate the type or style of work for which a person might be suited, need to be accurately translated, but may not need to meet the same exacting standards.

Finally, when interpretation is needed and is reasonable, it should be provided in a timely manner. To be meaningfully effective, language assistance should be timely. While there is no single definition for ''timely'' that is applicable to all types of interactions at all times by all recipients, one clear guide is that the language assistance should be provided at a time and place that avoids the effective denial or the imposition of an undue burden on or delay in important rights, benefits, or services to the LEP person. For example, when the timeliness of services is important, such as with certain activities of DOL recipients providing income security, health, and safety services, and when important programmatic rights, such as eligibility for UI benefits, are at issue, a recipient would likely not be providing meaningful access if it had one bilingual staff person available one day a week to provide the service. Such conduct would likely result in delays for LEP persons that would be significantly greater than those for English proficient persons. Conversely, where access to or exercise of a service, benefit, or right is not effectively precluded by a reasonable delay, language assistance can likely be delayed for a reasonable period.

Hiring Bilingual Staff. When particular languages are encountered often, hiring bilingual staff offers one of the best, and often most economical, options. Recipients can, for example, fill public contact positions, such as One-Stop Career Center receptionists or UI claims examiners, with staff who are bilingual and competent to communicate directly with LEP persons in the appropriate language. If bilingual staff is also used to interpret between English speakers and LEP persons, or to orally interpret written documents from English into another language, they should be competent in the skill of interpreting. Being bilingual does not necessarily mean that a person has the ability to interpret. In addition, there may be times when the role of the bilingual employee may conflict with the role of an interpreter (for instance, a bilingual hearings examiner would probably not be able to perform effectively the role of an administrative hearing interpreter and hearings examiner at the same time, even if the hearings examiner were a qualified interpreter). Effective management strategies, including any appropriate adjustments in assignments and protocols for using bilingual staff, can ensure that bilingual staff is fully and appropriately utilized. When an analysis of the four factors leads to a conclusion that the provision of services through bilingual staff is not a reasonable step, the recipient still should consider other options for providing meaningful access to LEP persons.

Hiring Staff Interpreters. Hiring interpreters may be most helpful where there is a frequent need for interpreting services in one or more languages. Depending on the facts, sometimes it may be necessary and reasonable to provide on-site interpreters to communicate effectively with LEP persons.

Contracting for Interpreters. Contract interpreters may be a cost-effective option when there is no regular need for a particular language skill. In addition to commercial and other private providers, many community-based organizations provide interpretation services for particular languages. Contracting with and providing training regarding the recipient's programs and

[10] Consecutive interpretation is interpretation of sentences/phrases immediately after they are spoken, where the original speaker interrupts the presentation to permit the interpretation. Simultaneous interpretation (sometimes referred to as UN-type translations) involves interpretation occurring at the same time as the original spoken text, where the original speaker does not stop or interrupt their presentation to permit the interpretation. Summarization involves an interpreter listening to the original speaker in another language and then summarizing the essence of what was said, not what was actually said. Summary interpretations are generally disfavored by professional interpreters or translators. Sight translation involves the translation of written text/documents into spoken text based on a visual review of the original form.

[11] Many languages have ''regionalisms,'' or differences in usage. For instance, a word that may be understood to mean something in Spanish for someone from Cuba may not be so understood by someone from Mexico. In addition, because there may be languages that do not have an appropriate direct interpretation of some programmatic or legal terms, the interpreter should be so aware and be able to provide the most effective interpretation. The interpreter should likely make the recipient aware of such an issue so that the interpreter and the recipient can then develop a consistent and appropriate set of descriptions of these terms in the target language that can be used in future encounters.

[12] For those languages in which no formal accreditation or certification currently exists, recipients should consider a formal process for establishing the credentials of the interpreter.

processes to these organizations can be a cost-effective option for providing language services to LEP persons from those language groups.

Using Telephone Interpreter Lines. Telephone interpreter service lines often offer speedy interpreting assistance in many different languages. They may be particularly appropriate where the mode of communicating with an English proficient person would also occur over the phone. Although telephonic interpretation services are useful in many situations, it is important to ensure that, when using such services, the interpreters are competent to interpret any technical or legal terms specific to a particular program that may be important to the conversation. Nuances in language and non-verbal communication can often assist an interpreter and cannot be recognized over the phone. Video teleconferencing may sometimes help to resolve this issue. In addition, where documents are being discussed, it is important to give telephonic interpreters adequate opportunity to review the documents prior to the discussion. Any other logistical problems should also be anticipated.

Using Community Volunteers. In addition to consideration of bilingual staff, staff interpreters, or contract interpreters (either in-person or by telephone) as options to ensure meaningful access by LEP persons, use of recipient-coordinated community volunteers, working with, for instance, community-based organizations may provide a cost-effective supplemental language assistance strategy under appropriate circumstances. They may be particularly useful in providing language access for a recipient's less critical programs and activities. To the extent the recipient relies on community volunteers, it is often best to use volunteers who are trained in the information or services of the program and can communicate directly with LEP persons in their language. Just as with all interpreters, community volunteers used to interpret between English speakers and LEP persons, or to orally translate documents, should be competent in the skill of interpreting and knowledgeable about applicable confidentiality and impartiality rules. Recipients should consider formal arrangements with community-based organizations that provide volunteers to address these concerns and to help ensure that services are available on a regular basis.

Use of Family Members, Friends, or Other Community Members as Interpreters. Although recipients should not plan to rely on a LEP person's family members, friends, or other informal interpreters to provide language assistance services to important programs and activities, where LEP persons so desire, they should be permitted to use, at their own expense, interpreters of their own choosing (whether a professional interpreter, family member, friend, or other informal interpreter) in place of or as a supplement to the free language services expressly offered by the recipient. LEP persons may feel more comfortable when a trusted family member, friend, or other community member acts as an interpreter. In addition, in exigent circumstances that are not reasonably foreseeable, temporary use of interpreters not provided by the recipient may be necessary. However, with proper planning and implementation, recipients should be able to avoid most of these situations.

Recipients, however, should take special care to ensure that family, friends, and other informal interpreters are appropriate in light of the circumstances and subject matter of the program, service or activity. The recipients' own interests in accurate interpretation should also be considered when deciding whether family, friends, and other informal interpreters are appropriate. In many circumstances, family members (especially children), friends, or other informal interpreters are not competent to provide quality and accurate interpretations. Issues of confidentiality, privacy, or conflict of interest may also arise. LEP individuals may feel uncomfortable revealing or describing sensitive, confidential, or potentially embarrassing family, employment history, or financial information to a family member, friend, or member of the local community. For these reasons, when oral language services are necessary, recipients should generally offer competent interpreter services free of cost to the LEP person. While issues of competency, confidentiality, and conflict of interest in the use of family members (especially children), friends, or other informal interpreters often make their use inappropriate, the use of these individuals as interpreters may be an appropriate option where proper application of the four factors would lead to a conclusion that recipient-provided services are not necessary. An example of this is an optional ''Dress for Success'' workshop offered by a One-Stop Career Center where there is such a small number and/or proportion of LEP persons eligible to be served and there is no available bilingual staff, volunteers, or interpreters available. There, the importance and nature of the activity may be relatively low and unlikely to implicate issues of confidentiality, conflict of interest, or the need for accuracy. In addition, the resources needed and costs of providing language services may be high. In such a setting, a LEP person's use of family, friends, or others may be appropriate.

If a LEP person voluntarily chooses to provide his or her own interpreter, a recipient should consider whether a record of that choice and of the recipient's offer of assistance should be kept. Where precise, complete, and accurate interpretations or translations of information and/or testimony are critical for adjudicatory or legal reasons, or where the competency of the LEP person's interpreter is not established, a recipient might decide to provide its own, independent interpreter, even if a LEP person wants to use his or her own interpreter as well. Extra caution should be exercised when the LEP person chooses to use a minor as the interpreter. While the LEP person's decision should be respected, there may be additional issues of competency, confidentiality, or conflict of interest when the choice involves using children to interpret. The recipient should take care to ensure that the LEP person's choice is voluntary, that the LEP person is aware of the possible problems if the preferred interpreter is a minor child, and that the LEP person knows that a competent interpreter could be provided by the recipient at no cost.

B. Written Language Services (Translation)

Translation is the replacement of a written text from one language (source language) into an equivalent written text in another language (target language).

What Documents Should be Translated? After applying the four-factor analysis, a recipient may determine that an effective LEP plan for its particular program or activity includes the translation of vital written materials into the language of each frequently-encountered LEP group eligible to be served and/or likely to be affected by the recipient's program. Such written materials could include:

- Applications to participate in a recipient's program or activity or to receive recipient benefits or services;
- Written tests that do not assess English language competency, but test competency for a particular license, job,

or skill for which English language proficiency is not required;[13]

- Consent and complaint forms;
- List of partners at a One-Stop Career Center and services provided;
- Letters containing important information regarding participation in a program or activity;
- Notices pertaining to the reduction, denial or termination of services or benefits and of the right to appeal such actions;
- Notices that require a response from beneficiaries;
- Information on the right to file complaints of discrimination;
- Information on the provision of services to individuals with disabilities;
- State wage and hour and safety and health enforcement and information materials;
- Notices advising LEP persons of the availability of free language assistance; and
- Other outreach materials.

Whether or not a document (or the information it provides and/or solicits) is ''vital'' may depend upon the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner. For instance, a description of books contained in the resource room of a One-Stop Career Center would not generally be considered vital, whereas applications for Unemployment Insurance or information about safety and health requirements could be considered vital. Where appropriate, recipients are encouraged to create a plan for consistently determining, over time and across its various activities, what documents are ''vital'' to the meaningful access of the LEP populations they serve.

Classifying a document as vital or non-vital is sometimes difficult, especially in the case of outreach materials like brochures or other information on rights and services. Awareness of rights or services is an important part of ''meaningful access.'' Lack of awareness that a particular program, right, or service exists may effectively deny LEP individuals meaningful access. Thus, where a recipient is engaged in community outreach activities in furtherance of its programs or services, it should regularly assess the needs of the populations frequently encountered or affected by the program or service to determine whether certain critical outreach materials should be translated. Community organizations may be helpful in determining what outreach materials may be most helpful to translate. In addition, the recipient should consider whether translations of outreach material may be made more effective when done in tandem with other outreach methods, including utilizing the ethnic media, schools, faith-based and other community organizations to spread the message.

Sometimes a document includes both vital and non-vital information. This may be the case when the document is very large. It may also be the case when the title and a phone number for obtaining more information on the contents of the document in frequently-encountered languages other than English is critical, but the document is sent out to the general public and cannot reasonably be translated into many languages. Thus, vital information may include, for instance, the provision of information in appropriate languages other than English regarding where a LEP person might obtain an interpretation or translation of the document.

Into What Languages Should Documents be Translated? The languages spoken by the LEP individuals with whom the recipient has contact determine the languages into which vital documents should be translated. A distinction should be made, however, between languages that are frequently encountered by a recipient and less commonly-encountered languages. Many recipients serve communities in large cities or across the country or operate web-based, self-service systems as an adjunct to their in-person delivery systems that also have a regional or national reach. They regularly serve LEP persons who speak dozens and sometimes over 100 different languages. To translate all written materials into all of those languages is unrealistic. Although recent technological advances have made it easier for recipients to store and share translated documents, such an undertaking would incur substantial costs and require substantial resources. Nevertheless, well-substantiated claims of lack of resources to translate all vital documents into dozens of languages do not necessarily relieve a recipient of the obligation to translate those documents into at least several of the more frequently-encountered languages and to set benchmarks for continued translations into the remaining languages over time. As a result, the extent of a recipient's obligation to provide written translations of documents should be determined by the recipient on a case-by-case basis, looking at the totality of the circumstances in light of the four-factor analysis. Because translation is a one-time expense, consideration should be given to whether the upfront cost of translating a document (as opposed to oral interpretation) should be amortized over the likely lifespan of the document when applying this four-factor analysis. The length of a document's lifespan and the volume of new documents requiring translation may also be a factor in this determination. For example, in transaction-based self-service websites, such as labor exchange/job matching, the lifespan of a typical document such as a job order may only be 30 days and the volume of such documents may easily number 1,000 or more each day. In such circumstances, depending on the four factors, recipients might consider translating only certain portions of such documents and/or providing information in appropriate languages on how to obtain free language assistance, if the technology allows.

Competence of Translators. As with oral interpreters, translators of written documents should be competent. Many of the same considerations apply. However, the skill of translating is very different from the skill of interpreting, and a person who is a competent interpreter may or may not be competent to translate.

Particularly where vital documents are being translated, competence can often be achieved by use of certified translators. Certification or accreditation may not always be possible or necessary.[14] Competence can often be ensured by having a second, independent translator ''check'' the work of the primary translator. Alternatively, one translator can translate the document, and a second, independent translator could translate it back into English to check that the appropriate meaning has been conveyed. This is called ''back translation.''

Translators should understand the expected reading level of the audience and, where appropriate, have

[13] Test translation raises technical testing issues and needs to be done in an appropriate manner if the test is to retain validity and reliability. Some tests are available in different languages. For example, the GED is available in Spanish and French, as well as English. So recipients may be able to check for the availability of tests in other languages from the test developer. Where no test is available in a language and translation is not immediately possible, it might be more appropriate to evaluate a LEP individual with another test or procedure that does not inappropriately implicate their limited English skills.

[14] For those languages in which no formal accreditation currently exists, a particular level of membership in a professional translation association can provide some indicator of professionalism.

fundamental knowledge about the target language group's vocabulary and phraseology. Sometimes direct translation of materials results in a translation that is written at a much more difficult level than the English language version or has no relevant equivalent meaning.[15] Community organizations may be able to help consider whether a document is written at a good level for the audience. Likewise, consistency in the words and phrases used to translate terms of art, legal, or other technical concepts helps avoid confusion by LEP individuals and may reduce costs. Creating or using already-created glossaries of commonly-used terms may be useful for LEP persons and translators and cost effective for the recipient. Providing translators with examples of previous accurate translations of similar material by the recipient, other recipients, or federal agencies may be helpful.

The quality and accuracy of language services is part of the appropriate analysis of LEP services required. For instance, documents that are simple and have no legal or other consequence for LEP persons who rely on them may use translators that are less skilled than important documents with legal or other information upon which reliance has important consequences (including, *e.g.*, information or documents of DOL recipients regarding the provision of income security benefits, such as UI, and health and safety training). The permanent nature of written translations, however, imposes additional responsibility on the recipient to ensure that the quality and accuracy permit meaningful access by LEP persons.

VII. Elements of an Effective Plan on Language Assistance for LEP Persons

After completing the four-factor analysis and deciding what language assistance services are appropriate, a recipient should develop an implementation plan to address the identified needs of the LEP populations they serve.[16] Recipients have considerable flexibility in developing this plan. A written plan, while not a requirement, can be an important tool for a recipient. The development and maintenance of a periodically-updated written plan on language assistance for LEP persons (''LEP plan'') for use by recipient employees serving the public will likely be the most appropriate and cost-effective means of documenting compliance and providing a framework for the provision of timely and reasonable language assistance. Moreover, such written plans would likely provide additional benefits to a recipient's managers in the areas of training, administration, planning, and budgeting. These benefits should lead most recipients to document in a written LEP plan their language assistance services and how staff and LEP persons can access those services. Despite these benefits, certain DOL recipients, such as recipients serving very few LEP persons and recipients with very limited resources, may choose not to develop a written LEP plan. However, the absence of a written LEP plan does not obviate the underlying obligation to ensure meaningful access by LEP persons to a recipient's program or activities. Accordingly, in the event that a recipient elects not to develop a written plan, it should consider alternative ways to articulate in some other reasonable manner a plan for providing meaningful access. Entities having significant contact with LEP persons, such as schools, faith-based organizations, community groups, and groups working with new immigrants, can be very helpful in providing important input into this planning process from the beginning.

The following five elements may be helpful in designing a LEP plan and are typically part of an effective implementation plan.

(1) Identifying LEP Individuals Who Need Language Assistance

The first two factors in the four-factor analysis require an assessment of the number or proportion of LEP individuals eligible to be served or encountered and the frequency of encounters. This requires a recipient to identify LEP persons with whom it has contact.

One way to determine the language of communication is to use language identification cards (or ''I speak cards''), which invite LEP persons to identify their language needs to staff. Such cards, for instance, might read ''I speak Spanish'' in both Spanish and English, ''I speak Vietnamese'' in both English and Vietnamese, etc. To reduce costs of compliance, the federal government has made a set of these cards available on the Internet. The Census Bureau ''I speak cards'' can be found and downloaded at *http://www.usdoj.gov/crt/cor/13166.htm*. When records are normally kept of past interactions with members of the public, the language of the LEP person can be included as part of the record. In addition to helping employees identify the language of LEP persons they encounter, this process will help in future applications of the first two factors of the four-factor analysis. In addition, posting notices in commonly encountered languages notifying LEP persons of the availability of language assistance will encourage them to self-identify.

Recipients should also consider circumstances in which, although the participant and/or beneficiary can communicate effectively in English, assistance may be needed when interacting with other pertinent individuals. For example, if a youth under the age of eighteen needs a parent's signature to participate in a summer employment program, language assistance may be necessary to provide information and obtain the necessary permission. Recipients should also be aware of external circumstances that may impact the number of persons (LEP or otherwise) seeking government assistance. For example, recipients may experience an ebb and flow of persons working in agricultural jobs depending on the season, the success of harvest, and other factors such as weather (droughts or floods). Changes in the economy may disproportionately force low-income individuals (as LEPs tend to be) to turn to government programs for assistance.

(2) Language Assistance Measures

An effective LEP plan would likely include information about the ways in which language assistance will be provided. For instance, recipients may want to include information on at least the following:

- Types of language services available;
- How staff can obtain those services;
- How to respond to LEP callers;

[15] For instance, there may be languages that do not have an appropriate direct translation of some programmatic or legal terms and the translator should be able to provide an appropriate translation. The translator should likely also make the recipient aware of this. Recipients can then work with translators to develop a consistent and appropriate set of descriptions of these terms in the language that can be used again, when appropriate. Recipients will find it more effective and less costly if they try to maintain consistency in the words and phrases used to translate terms of art and legal or other technical concepts. Creating or using already-created glossaries of commonly used terms may be useful for LEP persons and translators and cost-effective for the recipient. Providing translators with examples of previous translations of similar material by the recipient, other recipients, or federal agencies may be helpful.

[16] Certain recipients of DOL financial assistance are required, per 29 CFR 37.54, to establish and adhere to a Methods of Administration (MOA). Per the regulations, MOAs must be in writing, reviewed and updated every two years as required by Section 37.55, and, at a minimum, describe how the state programs and recipients have satisfied the requirements of regulations, including those found at Sections 37.35 and 37.42.

• How to respond to written communications from LEP persons;

• How to respond to LEP individuals who have in-person contact with recipient staff; and

• How to ensure competency of interpreters and translation services.

(3) Training Staff

Staff should know their obligations to provide meaningful access to information and services for LEP persons. An effective LEP plan would likely include training to ensure that:

• Staff know about LEP policies and procedures; and

• Staff having contact with the public are trained to work effectively with in-person and telephone interpreters.

Recipients may want to include this training as part of the orientation for new employees. It is important to ensure that all employees in public contact positions are properly trained. Recipients have flexibility in deciding the manner in which the training is provided. The more frequent the contact with LEP persons, the greater the need will be for in-depth training. Staff with little or no contact with LEP persons may only have to be aware of the LEP plan. However, management staff, even if they do not interact regularly with LEP persons, should be fully aware of and understand the plan so they can reinforce its importance and ensure its implementation by staff.

(4) Providing Notice to LEP Persons

Once a recipient has decided, based on the four factors, that it will provide certain language services, it is important for the recipient to let LEP persons know that those services are available and that they will be offered free of charge. Recipients should provide notice of the availability of language assistance services in language(s) that LEP persons will understand. Examples of notification that recipients should consider include:

• Posting signs in intake areas and other entry points. When language assistance is needed to ensure meaningful access to information and services, it is important to provide notice in appropriate languages in intake areas or initial points of contact so that LEP persons can learn how to access those language services. This is particularly true in areas with high volumes of LEP persons seeking access to certain workforce and income security programs, services or activities run by DOL recipients. For instance, signs in One-Stop Career Centers could state that free language assistance is available. The signs should be translated into the most common languages encountered. They should explain how to obtain the language help.[17]

• Stating in outreach documents that language services are available from the recipient. Announcements could be in, for instance, brochures, booklets, and in other outreach and recruitment information. These statements should be translated into the most common languages and could be ''tagged'' onto the front of common documents.

• Working with community-based organizations and other stakeholders to inform LEP individuals of the recipients' programs and activities, including the availability of language assistance services.

• Using a telephone voice mail menu. The menu could be in the most common languages encountered. It should provide information about available language assistance services and how to access them.

• Including notices in local newspapers in languages other than English.

• Airing notices on non-English language radio and television stations about the availability of language assistance and how to access it.

• Making presentations and/or posting notices at schools, faith-based and other community organizations.

(5) Monitoring and Updating the LEP Plan

Recipients should, where appropriate, have a process for determining, on an ongoing basis, whether new documents, programs, services, and activities need to be made accessible for LEP individuals, and they may want to provide notice of any changes in services to the LEP public and to employees. In addition, recipients should consider whether changes in demographics, types of services, or other factors require annual reevaluation of LEP plans. Less frequent reevaluation may be more appropriate where demographics, services, and needs are more static. One good way to evaluate the LEP plan is to seek feedback from the community. In their reviews, recipients may want to consider assessing changes in:

• Current LEP populations in service area or population affected or encountered;

• Frequency of encounters with LEP language groups;

• Nature and importance of activities to LEP persons;

• Availability of resources, including technological advances and sources of additional resources, and the costs imposed;

• Whether existing assistance is meeting the needs of LEP persons;

• Whether staff knows and understands the LEP plan and how to implement it;

• Legislation or program requirements governing the recipient's program or activity; and

• Whether identified sources for assistance are still available and viable.

In addition to these five elements, effective plans set clear goals, management accountability, and opportunities for community input and planning throughout the process.

VIII. Voluntary Compliance Efforts

The goal for Title VI and Title VI regulatory enforcement is to achieve voluntary compliance. The requirement to provide meaningful access to LEP persons is enforced and implemented by DOL through the procedures identified in the Title VI and Section 188 regulations. These procedures include complaint investigations, compliance reviews, efforts to secure voluntary compliance, and technical assistance.

DOL's Civil Rights Center (CRC) enforces Title VI and Section 188 through the procedures identified in the regulations in 29 CFR parts 31 and 37. The regulations state that CRC will investigate any complaint, report or other information that alleges or indicates possible noncompliance with Title VI and Section 188. If the investigation results in a finding of compliance, CRC will inform the recipient in writing of this determination, including the basis for the determination. If the investigation results in a finding of noncompliance, CRC will inform the recipient of the noncompliance in a Letter of Findings that sets out the areas of noncompliance and the steps that must be taken to correct the noncompliance. At this stage, CRC will attempt to secure voluntary compliance through informal means. If the matter cannot be resolved informally, compliance may be effectuated through (a) the termination of federal assistance after the recipient has been given an opportunity for an administrative hearing; (b) referral to DOJ for injunctive relief or other enforcement proceedings; or (c) any other means authorized by law. CRC has a legal obligation to seek voluntary compliance in resolving cases and cannot seek the termination of funds until it has engaged in voluntary compliance efforts and has determined that compliance cannot be secured voluntarily.

[17] The Social Security Administration has made such signs available at: *http://www.ssa.gov/multilanguage/langlist1.htm*. These signs could be modified for recipient use.

CRC engages in voluntary compliance efforts and provides technical assistance to recipients at all stages. During efforts to secure voluntary compliance, CRC will propose reasonable timetables for achieving compliance and will consult with and assist recipients in exploring cost effective ways of coming into compliance by increasing awareness of emerging technologies and by sharing information on how other recipients have addressed the language needs of diverse populations. In determining a recipient's compliance with Title VI and Section 188, CRC's primary concern is to ensure that the recipient's policies and procedures overcome barriers resulting from language differences that would deny LEP persons meaningful opportunities to participate in and access programs, services and benefits. A recipient's appropriate consideration of the methods and options discussed in this Guidance will be viewed by CRC as evidence of a recipient's willingness to comply with its Title VI and Section 188 obligations.

While all recipients must work toward building systems that will ensure access for LEP individuals, DOL acknowledges that the implementation of a comprehensive system to serve LEP individuals is a process and that a system will evolve over time as it is implemented and periodically reevaluated. As recipients take reasonable steps to provide meaningful access to federally assisted programs and activities for LEP persons, DOL will look favorably on intermediate steps recipients take that are consistent with this Guidance, and that, as part of a broader implementation plan or schedule, move their service delivery systems toward providing full access to LEP persons. This does not excuse noncompliance but instead recognizes that full compliance in all areas of a recipient's activities and for all potential language minority groups may reasonably require a series of implementing actions over a period of time. However, in developing any phased implementation schedule, DOL recipients should ensure that the provision of appropriate assistance for significant LEP populations or with respect to activities having a significant impact on the health, safety, legal rights, or livelihood of beneficiaries is addressed first. Recipients are encouraged to document their efforts to provide LEP persons with meaningful access to federally assisted programs and activities.

Appendix—Application to Specific Types of Recipients

This Appendix provides examples of how the meaningful access requirement of the Title VI and Section 188 of WIA regulations applies to state workforce agencies and other recipients of DOL financial assistance. These examples highlight best practices and ideal approaches to serving LEP individuals in a variety of situations. It is important to note that not all recipients may find these approaches useful or necessary once they apply the four-factor analysis to their individual situation. This Appendix also suggests ways that DOL recipients can apply the four-factor analysis to a range of encounters with the public as the responsibility for providing language services differs depending on the program or activity. The four factors are:

- The number or proportion of LEP persons served or encountered in the eligible service population;
- The frequency with which LEP individuals come in contact with the program;
- The nature and importance of the program, activity, or service provided by the program; and
- The resources available to the recipient and costs.

This Appendix is also designed to help DOL recipients identify the population to be considered when assessing the types of language services to provide. It then offers guidance and examples on how to apply the four-factor analysis to specific requirements of DOL-assisted programs and services, such as:

- Receiving and responding to requests for information and services;
- Applications for benefits such as trade and Unemployment Insurance benefits;
- Adjudications;
- Notifications of decisions;
- Intake, orientation and assessment;
- Training services; and
- Community outreach.

Appendix—Application of LEP Guidance for Specific Types of DOL Recipients

While a wide range of entities receive federal financial assistance through DOL, most of DOL's assistance is awarded to Governors or local chief elected officials in the form of formula or competitive grants for the provision of training, including job training, and income support programs. This Appendix provides examples to demonstrate how DOL recipients might apply the four-factor analysis. The examples in this Appendix are not meant to be exhaustive. The four-factor analysis requires a balancing, given all of the facts. Each different situation will present some unique aspects. The examples are intended only to show how the four-factor analysis may be applied in some situations.

The requirements of the Title VI and Section 188 regulations, as clarified by the LEP Guidance, supplement, but do not supplant, other statutory or regulatory provisions that may require LEP services. Rather, the LEP Guidance clarifies the obligation under both the Title VI and Section 188 regulations to address, in appropriate circumstances and in a reasonable manner, the language assistance needs of LEP individuals.

For the vast majority of the public, exposure to federally-assisted job training or income support programs includes applying for and receiving Unemployment Insurance (UI) benefits or conducting job search activities through the One-Stop Career System. For a smaller number, exposure includes participation in a job training program under WIA or the Trade Act of 1974 including Trade Adjustment Assistance (TAA). The common thread running through these and other interactions with the federally-assisted workforce system is the exchange of information and services. LEP individuals' encounters with One-Stop Career Centers, including UI Call Centers, are covered by Title VI because they are funded wholly or in part by DOL. This Guidance focuses on the requirement that DOL recipients communicate effectively with persons who are LEP to ensure that they have meaningful access to the workforce investment system, including, for example, understanding how to apply for job training and/or UI benefits.

Many DOL recipients already provide language services in a wide variety of circumstances. For example, in areas where significant LEP populations reside, One-Stop Career Center staff may utilize forms and notices in languages other than English and/or they may employ bilingual front-line staff. Recipients' current practices can form a strong basis for applying the four-factor analysis and complying with Title VI and WIA Section 188 regulations.

In general, when providing language services, DOL recipients may: (1) Make available the staff and materials necessary to supply required language services; (2) choose to require an entity with which they have contracted to provide the services; or (3) contract with another entity to provide those services. Recipients have a wide variety of options for providing interpreter and translation services appropriate to the particular situation. Using bilingual staff competent to interpret in person or over the phone is one option. Additionally, particular recipients may enter into agreements with local colleges and universities, interpreter services, and/or community organizations to provide competent paid or volunteer translators.

1. General Principles

The touchstone of the four-factor analysis is reasonableness based upon the specific purposes, needs, and capabilities of the DOL recipient and an appreciation of the nature and particular needs of the LEP population served. Accordingly, the four-factor analysis cannot provide a single uniform answer about how service to LEP persons must be provided in all programs or activities in all situations or to what extent such service need be provided.

Knowledge of local conditions and community needs is critical in determining the type and level of language services needed. The following general points should

assist DOL recipients in correctly applying the four-factor analysis to the wide range of services provided in their particular communities.

a. Permanent Versus Seasonal Populations

In assessing factor one, the number or proportion of LEP individuals, DOL recipients should consider any temporary but significant changes in a community's demographics. In many areas, resident populations change over time or according to season. For example, in some resort communities, populations swell during peak vacation periods, many times exceeding the number of permanent residents in the area. In other communities, primarily agricultural areas, transient populations of agricultural workers require increased workforce investment services during planting and harvest seasons. This dynamic demographic ebb and flow can also dramatically change the size and nature of the LEP community that is likely to come into contact with workforce entities. Thus, workforce entities may not want to limit their analysis to numbers and proportions of permanent residents.

Example: A rural community has a permanent population of 30,000, of which seven percent is Hispanic. Based on census data and on information from the contiguous school district, only 15 percent of the Hispanic population is estimated to be LEP. Thus, the total estimated permanent LEP population is 315 persons or approximately one percent of the total permanent population. Under the four-factor analysis, a workforce entity could reasonably conclude that the small number of LEP persons makes the translation of vital documents and/or employment of bilingual staff unnecessary. However, during the spring and summer planting and harvest seasons, the local population swells to 40,000 due to the influx of seasonal agricultural workers. Of this temporary population, about 75 percent is Hispanic and about 50 percent of that number is LEP. According to data supplied by the contiguous school district and a migrant worker community group, during the planting and harvest seasons, the community's LEP population increases to over ten percent of all residents. In this case, a DOL recipient should consider whether it is necessary to translate vital written documents into Spanish. In addition, the predictability of contact during those seasons makes it important for the community to review its interpretative services to ensure meaningful access for LEP individuals.

b. Target Audiences

For most workforce investment services, the target audience is defined in geographic rather than programmatic terms. However, some services may be targeted to reach a particular audience (*e.g.*, out-of-school youth or migrant and seasonal farmworkers). Also, within the larger geographic area covered by a workforce entity, certain areas or neighborhoods may have concentrations of LEP persons. In these cases, even if the overall number or proportion of LEP individuals in the area is low, the frequency of contact may be higher for certain areas or programs. Thus, the second factor, frequency of contact, should be considered in light of the specific program or the geographic area served.

Example: A community-based organization (CBO) is partnering with a local One-Stop Career Center to provide services to dislocated workers who have lost their jobs due to several recent textile plant closures. The LEP population of the community is estimated at only three percent. However, the LEP population of the workers dislocated by the closures is 35 percent, the vast majority of whom speak Vietnamese. As the target population for this CBO is confined to the dislocated workers, the number or proportion of LEP persons in the eligible service population would be calculated based on these workers. The applicable LEP factor would be the frequency with which LEP individuals come in contact with the program, which in this instance would involve a much higher percentage of LEP individuals than that of the general population. Further, because the Vietnamese LEP population is concentrated in one or two main areas of the town, the CBO should expect the frequency of contact with Vietnamese LEP individuals, in general, to be quite high in those areas, and it should apply the four-factor analysis accordingly with respect to the services it provides.

c. Importance of Service/Information

DOL recipients play a critical role in providing workforce services, income support, and health and safety training for many Americans. UI, health and safety services provided through the Occupational Safety and Health and Mine Safety and Health Administrations, information and enforcement of State and local wage and hour laws and other workers' rights enforcement issues taken on by recipients, and employment services rank high on the critical/non-critical continuum. However, this does not mean that information about all services and activities performed by workforce entities must be equally available in languages other than English. While clearly important to the ultimate success of the workforce investment system, certain activities do not have the same direct impact on the provision of core workforce investment services. The more important the program or activity or the greater the possible consequences of the contact for LEP individuals, the more likely language assistance services will be necessary.

Example: The Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA) provide grants to recipients to conduct safety and health training to individuals employed in many dangerous occupations, such as construction and mining. Much of the training involves learning how to take precautions to avoid accidents or injuries while on the job. Where individuals could sustain bodily harm if training is not provided in an understandable language, the need for appropriate communication is extremely high.

There may be some instances in which the four-factor analysis of a particular portion of a recipient's program or activity leads to the conclusion that language services are not currently required. For instance, the four-factor analysis may not necessarily require that an advanced level computer course be given in languages other than English, if the language-related requirements for such an employment path is such that few, if any, LEP persons would benefit from the particular course even if it were made accessible to them and even if they are in the process of learning English (see Section V(3) above regarding such determinations), and if the other three factors also weigh against providing the service. However, a recipient may decide to provide other computer courses in languages other than English given demographics of the area and the potential benefit to the LEP population. Because the analysis is fact-dependent, the same conclusion may not be appropriate with respect to all computer courses or to other courses.

2. Applying the Four-Factor Analysis to the Full Spectrum of Services

While all workforce investment activities are important, the four-factor analysis requires some prioritizing so that language services are targeted where they are most needed depending on the nature and importance of the particular service provided. Workforce entities have a great deal of flexibility in determining how to best address outreach to their LEP populations. In order to determine what is reasonable under the four-factor analysis, consider that the obligation to provide language services increases where the importance of the activity is greater. Under this framework, critical areas for language assistance would include applications for UI or trade-related benefits and adjudications of issues regarding benefits. Systems for receiving and addressing complaints from the public are also important. Employment services are of great importance for persons who are not currently employed. Community outreach activities are hard to categorize and generally less critical than other activities unless barriers to participation (such as limited availability of language services) exist. With the importance of community partnerships and involvement, the four-factor analysis should be considered when evaluating the need for language services with respect to these programs.

a. Receiving and Responding to Requests for Assistance

Taking reasonable steps to provide meaningful access to workforce investment services will entail different things in different communities. For instance, in areas with significant LEP communities, some intake workers and claims examiners may need to be bilingual and capable of accurately interpreting in high stress situations. Recipients in areas with small LEP populations should still have a plan for serving persons who are LEP, which may involve a telephone interpretation service or include some other accommodation short of hiring bilingual staff. Signs and telephone voicemail systems should also be appropriate for the populations served.

Example: A One-Stop Career Center in a large city has bilingual staff that can interpret

the most frequently encountered languages. When LEP clients request services in less frequently encountered languages, a commercial telephone interpretation service is provided. Ten percent of the city's population is LEP, and sixty percent of the LEP population speaks Spanish. The One-Stop Career Center has many Spanish-speaking staff and a few staff that speak other languages. Forms are translated into Spanish. The recipient provides services to other non-English-speaking clients using a language bank, comprised of volunteers and bilingual staff employed by other Government entities who are competent translators and/or interpreters. This example may be one appropriate way of providing meaningful access for LEP individuals.

Example: A small One-Stop Career Center is operated by a recipient of DOL funds and located in an area where 15 percent of the population speak Spanish and may be LEP. Seven percent of the population in the service area speak various Chinese dialects and may be LEP. The One-Stop Career Center uses competent community volunteers to help translate vital outreach materials into Chinese (which is one written language despite many dialects) and Spanish. The One-Stop Career Center telephone system has a menu providing key information, such as location, in English, Spanish, and two of the most common Chinese dialects. Calls for immediate assistance are handled by bilingual staff. The One-Stop Career Center has one counselor and several volunteers fluent in Spanish and English. Some volunteers are fluent in different Chinese dialects and in English. The One-Stop Career Center works with community groups to access interpreters in the several Chinese dialects that they encounter. One-Stop Career Center staff train the community volunteers in the intake process and the specialized vocabulary needed to explain the services available. Volunteers sign confidentiality agreements. The One-Stop Career Center is looking for a grant to increase its language capabilities despite its limited resources. There have been no complaints of delayed or denied service on account of language barriers. This example may be one appropriate way of providing meaningful access for LEP individuals.

b. Delivering Labor Exchange Services

Currently, labor exchange services are being delivered through a wide variety of media, both electronic and paper-based. However, state and local workforce agencies are increasingly relying on Internet-based, self-help models of service delivery. While this method of service has the potential of benefiting the greatest number of job seekers while minimizing staff resources, key segments of the population are potentially excluded. Persons with limited language and literacy skills often have extra difficulty accessing services through the self-help, Internet-based systems. As such, a service plan is needed to develop alternative delivery systems. This can be done through incorporating one or more of the following strategies: (1) Having certain information translated; (2) incorporating a sufficient level of staff assistance to serve those persons that need assistance in accessing services electronically; or (3) providing direct one-on-one sessions with LEP applicants who are unable to access electronic information.

Example: A One-Stop Career Center in a moderately large city includes significant LEP populations whose native languages are Spanish, Korean, and Tagalog. One-Stop Career Center management officials could reasonably consider creating a resource list of individuals competent to interpret and ready to assist front-line staff dealing with LEP customers. This could be combined with developing language-appropriate written materials, such as an explanation of basic labor exchange activities and other services available at the One-Stop Career Center for use by LEP individuals who are literate in those languages. In other circumstances, it may be necessary to provide access to a telephone interpretation service.

Example: Job placement staff at a One-Stop Career Center assist employers interested in hiring LEP individuals who have completed ESL vocational training. In some instances, employers may have bilingual supervisors who can assure that safety precautions and explanations are provided in the individuals' primary language(s). In other locations, ''ethnic'' community-based organizations maintain lists of employers who have openings and are able to place LEP individuals without providing ESL or vocational training with businesses where the LEP individuals' primary language(s) is spoken. This example may be one appropriate way of providing meaningful access for LEP individuals.

Example: A large state, with an ethnically diverse population, operates a website as part of its overall delivery system which offers access to labor market information and provides labor exchange self-service for job seekers and employers. Because of the scope and reach of the Internet, the population eligible to be served by that website may easily include LEP individuals representing over 100 different languages. In this instance, the state translates key documents and forms on its website into the most significant languages, *e.g.*, representing five percent or more of the total eligible population to be served, and advertises its toll-free help line, which includes interpretation services, on the homepage of its website. Through the combination of its toll-free help line and its in-office delivery system, the state is able to provide information and services to LEPs in languages that are less commonly encountered. In this instance, the recipient takes into account, in conducting its four-factor analysis, its entire delivery system, not just one component. This example may be one appropriate way of providing meaningful access for LEP individuals.

c. Delivering Unemployment Insurance (UI) Services

The federal-state UI program created by the Social Security Act of 1935, offers the first line of defense against the ripple effects of unemployment. Payments made directly to eligible, unemployed workers ensure that at least a significant proportion of the necessities of life, most notably food, shelter and clothing, can be met on a week-to-week basis while the claimant searches for work. UI benefits provide temporary wage replacement that helps claimants to maintain their purchasing power and stabilize the economy.

(1). Initial Claims and Follow-Up Notices

State agencies that serve LEP claimants should consider the inherent communication impediments to gathering information from LEP persons throughout the UI claims process. During the initial claim process, it is necessary to collect basic information, such as the LEP person's name, address, employment information, and reason for separation from employment. It is also necessary to communicate with claimants throughout the life of their claims, and workforce agencies should evaluate their ability to provide appropriate services at all stages of the UI claim. Where few bilingual staff are available or in situations where the LEP person speaks a language not frequently encountered in the local area, telephone interpretation services may provide the most cost effective and efficient method of communication during the initial claim. However, subsequent correspondence and communication frequently entail written notices and claim forms. Depending on the size of the LEP population, it may be necessary to translate vital forms into other languages or to include a multilingual tag-line on correspondence not appropriately translated to inform claimants that free language services are available.

Example: A state agency operates a statewide Call Center for UI initial claims taking that receives 100,000 calls per year. The majority of the calls are from English speakers. Fifteen percent of the callers (15,000) do not speak English: 6,500 callers speak Spanish; 4,000 speak Vietnamese; 3,500 speak Cambodian; and the rest speak other languages (500 Russian, 100 French, 80 Tagalog, 20 German, and 300 speak other languages). The Call Center employs four Spanish speakers, two Vietnamese speakers and two Cambodian speakers. A voice response system directs the calls as appropriate to the bilingual staff. Calls from LEP claimants speaking other languages are directed to a commercial interpretation (telephone interpretation) service. The Call Center's bilingual employees are able to handle most calls from the three significant LEP language groups that they serve. Callers who speak English and any of the three languages for which translation is provided generally wait no longer than five minutes to speak with the staff. The system is monitored for wait times and performance. Follow-up correspondence such as letters, notices, and forms contain a tag-line in the languages of the three significant LEP groups and three other commonly encountered languages. The tag-line advises individuals of the importance of the information and provides a phone number to call for assistance. This example may be one appropriate way of providing meaningful access for LEP individuals.

(2). UI Benefits Rights Information (BRI)

State agencies provide UI benefits rights information to all claimants. The information is necessary to ensure that claimants

understand their rights and responsibilities under the state UI law.

Example: A state agency takes its UI claims in-person. It prints a Benefits Rights Information (BRI) pamphlet in English and in three other languages to serve the three significant LEP population groups in the state. After the initial claim is taken, the state agency provides the BRI in a group setting for all claimants. LEP individuals who speak the three significant languages attend separate groups in which the information is conveyed in the appropriate languages. Claimants who speak languages that are less prevalent receive the information through a telephone translation service. The state agency has also produced a video of the BRI in the three primary LEP groups' languages. The BRI video is available for viewing at the local library or at the local office. Claimants are advised that the BRI is important and that it is necessary that they hear and understand the BRI before filing claims for benefits. This example may be one appropriate way of providing meaningful access for LEP individuals.

(3). UI Determinations/Adjudications/Appeals

The purpose of the UI program is to provide temporary financial assistance to individuals who have lost their employment, who are able and available for work, and who meet other eligibility requirements of state law. As appropriate, claims adjudicators apply the legal test of the various requirements of the state law to the factual circumstances involved in each specific claim to issue a determination of eligibility. All state laws contain provisions permitting claimants to appeal determinations within a specified period of time. Because of the importance of accurate and timely information from UI claimants for eligibility determinations, formulating a successful policy for effectively communicating with LEP individuals is necessary.

Example: A workforce agency institutes a LEP plan that provides qualified interpreters, as necessary, for fact-finding at the initial determination stage and/or at an appeals hearing. Some of the interpretation is done using bilingual state agency staff, and some interpretation is handled by a number of individuals that are placed on a ''list of interpreters'' developed to assist when state staff is unavailable or when staff do not speak the particular language needed. The agency also has a contract with a telephone translation service, which is used as needed. The written determinations and decisions are printed in English and Spanish and ''tag-lines'' (an annotation) are included in four additional languages advising claimants of their appeal rights. Claimants are advised at the time of the initial claim that it is very important to read and understand correspondence they receive about UI, and they are encouraged to seek assistance by contacting the agency as necessary. The agency is able to handle telephonic inquiries languages other than English. These actions would constitute evidence of reasonable steps to ensure meaningful access to the UI benefits. This example may be one appropriate way of providing meaningful access for LEP individuals.

(4). UI Linkages to Reemployment Services

Facilitating reemployment of the UI claimant is a key objective of the UI system. Claimants therefore need to be aware of the types of services available and need to know how and where to access such services.

Example: A state agency profiles UI claimants to identify those most in need of reemployment services. Written notices to report for reemployment services are sent to those claimants who have been identified as needing these services and whom the agency has the capacity to serve. Claimants are given specific instructions to report to the agency or contact the agency through other means such as by telephone. Claimants must understand both the requirement that they contact the agency and their rights under state law because a failure to follow these instructions could result in the denial of UI benefits. A tag-line is included on all notices in the three primary languages advising the claimant of the importance of these services and of the fact that language assistance will be available free of charge. Translation and interpretation for LEP claimants is provided through telephone interpretation services, some bilingual staff, and community-based organizations as needed. One-Stop Career Centers that may subsequently refer claimants to other service providers ensure that the service providers are aware of the language needs of the LEP claimants. This example may be one appropriate way of providing meaningful access for LEP individuals.

d. Community Outreach

Community outreach activities are increasingly recognized as important to the ultimate success of a program that aims to serve the larger community. Thus, application of the four-factor analysis to community outreach activities can play an important role in ensuring that the purpose of these activities—to improve awareness of and participation in a program—is not thwarted due to lack of planned, reasonable steps to address the language needs of LEP persons.

Example: A state Employment Security Department (ESD) UI Division has implemented a many-faceted outreach program to inform Spanish-speaking LEP customers how to access UI benefits. Eight radio stations that reach the highest numbers of Hispanics are used to make public service announcements about ESD services. Inserts are placed in major Hispanic newspapers and magazines, and flyers on ESD services are distributed through community centers, faith-based organizations, and Hispanic businesses. Articles are printed in newspapers and magazines in Spanish and English on how to file UI claims by phone through the UI Telecenters. This example may be one appropriate way of providing meaningful access for LEP individuals.

Example: The Local Workforce Investment Board mobilizes faith and community-based organizations to spread the word about the upcoming public comment session on its five-year workforce investment plan in the six major languages spoken by LEP individuals in the area. Information about the upcoming meeting is delivered throughout the community in written notices (in each target language) as well as through public service announcements on radio and tv in these six target languages. This example may be one appropriate way of providing meaningful access for LEP individuals.

e. ESL Classes

English-as-a-second-language (ESL) classes are often useful and appropriate for LEP populations. ESL courses can serve as an important part of a proper LEP plan. However, the fact that ESL classes are provided does not necessarily obviate the need to provide meaningful access for LEP persons in other programs and services that the One-Stop Career Center provides.

f. Intake, Orientation and Assessment

Intake, orientation and assessment play a critical role not merely in the system's identification of LEP persons, but also in providing those persons with fundamental information about how to utilize the system and participate in education and training opportunities available. All individuals should be given the opportunity to be informed of the program's rules, obligations, and opportunities in a manner designed effectively to communicate these matters. An appropriate analogy is the obligation to communicate effectively with deaf persons, which is most frequently accomplished through sign language interpreters or written materials. Not every One-Stop Career Center will use the same method for providing language assistance. One-Stop Career Centers with large numbers of Spanish-speaking LEP persons may choose to translate written materials, notices, and other important orientation material into Spanish with oral instructions, whereas One-Stop Career Centers with very few such persons may choose to rely upon a telephonic interpretation service or qualified community volunteers to assist. Each person's LEP status and the language spoken should be recorded in the person's file. Although the LEP Guidance and Title VI are not meant to address literacy levels, recipients should be aware of literacy problems so that the appropriate language services are provided.

Example: A One-Stop Career Center is located in an area that has a five percent Haitian Creole-speaking LEP population and an eight percent Spanish-speaking LEP population. The One-Stop Career Center has developed intake videos in Haitian Creole and Spanish for staff to use when conducting orientation for new LEP persons who speak these languages. In addition, the One-Stop Career Center provides LEP persons with the opportunity to ask questions and discuss orientation information with bilingual staff who are competent in interpreting and who are either present at the orientation or patched in by phone to act as interpreters. The One-Stop Career Center has also made arrangements for LEP persons who do not speak Haitian Creole or Spanish. For such situations, the One-Stop Career Center has created a list of sources for interpretation, including staff, contract interpreters, university resources, volunteers, and a telephone interpretation service. Each person receives at least an oral explanation of the

services available in the One-Stop Career Center. This example may be one appropriate way of providing meaningful access for LEP individuals.

g. Providing More Intensive Employment and Training Services

An effective LEP plan should envision how a LEP person will move from receipt of core services to intensive services and then to training services. An effective LEP plan will envision accommodations along each step of the service continuum. For example, customized programs that combine Vocational ESL and skills-based vocational training may be appropriate depending upon the size of the LEP population and the need of individual LEP persons. If there are a significant number of LEP persons speaking a particular language in a local area, the One-Stop Career System should consider outreach to training providers that could provide classes in appropriate languages in One-Stop Career Centers and at employer sites. If there are far fewer LEP persons speaking a particular language, the recipient might consider the use of bilingual teachers, contract interpreters, community volunteers to interpret during the class, reliance on videos or written explanations in appropriate languages.

Example: A rural One-Stop Career Center has made a number of accommodations to serve LEP job-seekers. Services are provided both directly to the applicants and through a partner organization that has the capability to mobilize comprehensive services to assist LEP clients. The partner organization runs a special service center, which is considered part of the One-Stop Career System and is located near its main offices. The special center offers core employment services such as job placement, job-seeking/job-retention skills, and individual counseling to LEP clients as well as providing access to many other services, such as housing, transportation, childcare, legal services, counseling, interpretive services, and assistance with completing immigration and naturalization forms. Emergency referrals for healthcare, housing/shelter, and food are also made. The local One-Stop Career Center also routinely provides specialized resources to serve LEP dislocated workers, including bilingual assistance for UI and other financial aid, assessment of English language skills, and ESL career planning. The program utilizes the ESL capabilities available at the local community college and hires translators to assist the workers in developing individual plans, providing guidance, and in taking skill-building courses in new demand occupations. Customized ESL classes have been developed on specific work-related issues (for example, higher level ESL courses on job seeking and communicating in the workplace are offered). Students are also referred to both community-based ESL and an intensive for-credit immersion ESL course that runs five days a week, six hours a day, offered through the local community college. The local program has also developed a strong partnership with the State Bureau of Refugee Services to coordinate the provision of additional social services for LEP dislocated workers. This example may be one appropriate way of providing meaningful access for LEP individuals.

Example: A community college, which serves as a One-Stop Career Center, customizes its workforce services for LEP individuals. In particular, its dislocated worker program (of which eighteen percent of participants is LEP) has made accommodations in fourteen services that are now individualized to meet the specific needs of LEP participants. The services include: outreach and recruitment, rapid response, orientation, assessment, case management, self-sufficiency plan development, support services, vocational training, job search assistance, job development and placement, retention services, interagency coordination, basic skills training, and employer services. Changes in services have been developed through close collaboration between the workforce investment staff and the traditional ESL teachers at the community college. While ESL, adult basic education and GED courses are available to all participants; the LEP dislocated workers receive customized employment-related ESL training. The dislocated worker program also provides peer support training and counseling. This unique approach involves training peers—dislocated workers themselves—who are proficient in both the LEP participant's primary language and English to serve as translators, information providers, and counselors to the other dislocated workers. Another unique component of the services to LEP dislocated workers is the targeted industry model, which includes pre-training job shadowing and industry-related classroom activities. The program also provides training to employers on cultural differences and on creating multicultural work teams. Finally, the program has developed close relationships with community-based organizations serving immigrant populations to provide other services to LEP individuals. The community-based organizations provide additional employment services as well as information on a variety of youth and family services, which may be useful to dislocated worker participants. This example may be one appropriate way of providing meaningful access for LEP individuals.

h. Youth Programs

DOL provides funds to many youth programs to which the LEP Guidance applies. Recipients should also consider LEP parents when designing programs targeted to youth.

Example: A local workforce program serving former gang members has significantly altered its services to accommodate a large number of immigrant youth who have limited English proficiency and are transitioning from the juvenile justice system. In order to make all program elements accessible to these youth, program staff is fluent in multiple languages including Vietnamese, Cambodian, Spanish, and Laotian. Upon entry into the program, each youth is assessed using a specially designed risk assessment tool to gauge such factors as educational and employment skill levels, need for home-based support (which can include culturally appropriate interventions), counseling, and identification of personal assets and interests. Each youth receives an individualized service strategy after assessment. This example may be one appropriate way of providing meaningful access for LEP individuals.

[FR Doc. 03–13125 Filed 5–28–03; 8:45 am]

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Federal Register

Thursday,
May 29, 2003

Part V

Securities and Exchange Commission

17 CFR Part 241

Books and Records Requirements for Brokers and Dealers Under the Securities Exchange Act of 1934; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 241

[Release No. 34–47910]

Books and Records Requirements for Brokers and Dealers Under the Securities Exchange Act of 1934

AGENCY: Securities and Exchange Commission.

ACTION: Interpretation.

SUMMARY: The Securities and Exchange Commission is publishing guidance to clarify certain issues relating to broker-dealer books and records rules. Some of these issues have been raised as a result of the amendments to these rules that were adopted on October 26, 2001.

EFFECTIVE DATE: May 29, 2003.

FOR FURTHER INFORMATION CONTACT: Michael A. Macchiaroli, Associate Director, at (202) 942–0131; Thomas K. McGowan, Assistant Director, at (202) 942–4886; or Bonnie L. Gauch, Attorney, at (202) 942–0765; Office of Risk Management and Control, Division of Market Regulation, United States Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–1001.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 17(a)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') requires registered broker-dealers to make, keep, furnish, and disseminate reports the Securities and Exchange Commission (the ''Commission'') deems ''necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of this title.'' Rule 17a–3[1] and Rule 17a–4[2] under the Exchange Act (the ''Books and Records Rules'') specify minimum requirements with respect to the records that broker-dealers must make, and how long those records and other documents relating to a broker-dealer's business must be kept.

The Commission amended its Books and Records Rules on October 26, 2001[3] to clarify and expand recordkeeping requirements with respect to purchase and sale documents, customer records, associated person records, customer complaints, and certain other matters. The amendments expanded the types of records that broker-dealers must maintain and required broker-dealers to maintain or promptly produce certain records at each office to which those records relate. The amendments were designed to assist securities regulators, particularly State[4] securities regulators, when conducting sales practice examinations of broker-dealers. Certain interpretive questions have arisen regarding these amendments.

II. Interpretive Questions

The Commission has received questions from broker-dealers, industry representatives, and regulators, requesting clarification of certain requirements under the Books and Records Rules. These questions, along with the Commission's answers to these questions are as follows:

Question #1

New paragraphs (a)(6) and (a)(7) of Rule 17a–3 require a broker-dealer to create a record of each brokerage order and for each purchase or sale for the account of the broker-dealer showing, among other things, the time the order was received. Under Rules 17a–3(a)(6) and (a)(7), is the broker-dealer required to record the time of receipt of an order to purchase a mutual fund, variable annuity, or direct participation plan that is effected on a basis other than subscription—way where the purchase price is determined only once daily at the close of business?

Answer #1

If the time of receipt is material to an order, then the broker-dealer must record the time of receipt on the order ticket. Generally, for many types of transactions, the time of receipt may be material to the price or other terms of the execution of the order. For example, recording the time of receipt would be material if an intra-day time deadline existed that determined whether the order was priced as-of the date the order was received or the price as-of the next day. If the broker-dealer does not record the time of receipt of an order, the broker-dealer must be able to demonstrate that the time of receipt is not material to that order.

Question #2

New Rule 17a–3(a)(17) provides that each registered broker-dealer must create an account record for ''each account with a natural person as a customer or owner.'' Broker-dealers have specifically asked whether the term ''account with a natural person as a customer or owner'' would include accounts of a corporation, partnership, limited liability company, or trust, or a Uniform Gift/Transfer to Minor Act (commonly referred to as an UGMA or UTMA) account, IRA account, or 401k account?

Answer #2

The account record requirement of Rule 17a–3(a)(17) does not apply to an account for which the customer or owner is not a natural person, such as the account of a corporation, partnership, limited liability company, or REIT. Similarly, where the account is owned by the trustees of the trust or a trust that is a legal entity separate from the holders of its beneficial interests (which may be natural persons) the account record requirement does not apply. However, the term ''owner'' in Rule 17a–3(a)(17) would generally apply to an UGMA/UTMA account, an IRA account and a 401k account where the beneficiary of the account is a natural person.

We remind broker-dealers, however, that paragraph (a)(17)(i)(D) of Rule 17a–3 provides that the account record requirement only applies to accounts for which the broker-dealer is, or has within the past 36 months been, required to make a suitability determination under the Federal securities laws or under the requirements of a self-regulatory organization of which the broker-dealer is a member. If the firm has not been, within the past 36 months, required to make a suitability determination for recommendations about securities made to the customer of an account under federal laws or the requirements of a self-regulatory organization of which it is a member, then the firm would not be required to make the records described in new paragraph 17a–3(a)(17).

As noted in the Adopting Release, application of new paragraph 17a–3(a)(17) does not limit any other Federal law or regulation or SRO rule that requires that a broker-dealer collect information regarding its customers.[5]

Question #3

New Rule 17a–3(a)(17) applies to an ''account with a natural person as a customer or owner.'' Would the Commission consider a 401k account where the employer has established an omnibus account at the broker-dealer holding the assets of all its employees to be within the purview of this rule? How about a bank trust account where the bank has established an omnibus

[1] 17 CFR 240.17a–3.

[2] 17 CFR 240.17a–4.

[3] *See* Exchange Act Release No. 44992 (October 26, 2001), 66 FR 55818 (Nov. 2, 2001) (the ''Adopting Release'').

[4] Exchange Act § 3(a)(16) states, ''the term 'State' means any State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, or any other possession of the United States'' (15 U.S.C. 78c(a)(16)).

[5] *See* text accompanying note 43 in the Adopting Release. 66 FR 55818, at 55822 (Nov. 2, 2001).

account at the broker-dealer holding the co-mingled assets of the banks customers and the bank's customers are not aware that their assets are held by the broker-dealer?

Answer #3

No. The 401k account or bank trust account described above would not be subject to Rule 17a–3(a)(17).

Question #4

New Rule 17a–3(a)(17) provides that each registered broker-dealer must keep a record indicating that the broker-dealer has furnished all information required by paragraph (a)(17)(i)(A) to each customer or owner at specified intervals. To whom should this account record information be sent in the case of a trust?

Answer #4

In the case of a trust, the account record information should be sent to the same person that receives account statements for that account.

Question #5

A broker-dealer is required, pursuant to new paragraph 17a–3(a)(17)(i)(B), to provide a copy of the account record to the customer (i) Within 30 days after opening an account and thereafter at intervals no greater than every 36 months, and (ii) within 30 days after certain account record information has been changed. If one customer has a personal account, a separate IRA account, and a trust account for his child at the same broker-dealer, and has agreed in writing to receive account-related documentation, such as account statements, on a combined basis, may the firm meet its requirements under Rule 17a–3(a)(17) by combining in one mailing the account record information for all three accounts? Would the answer be different if spouses living at the same address each had a personal account and agreed to receive account documents on a combined basis for their personal accounts?

Answer #5

If the customer has agreed in writing to receive account-related documentation on a combined basis for multiple accounts at the same address, the broker-dealer may send account record information regarding each of those accounts to the customer in a combined mailing. However, the account record information should be separated by account so the customer can easily identify the account record information that relates to each account. If spouses living at the same address have agreed to receive account documents on a combined basis for their personal accounts, the broker-dealer may send account record information regarding each of those accounts to the customer in a combined mailing.

Question #6

New paragraph (a)(17)(iii) of Rule 17a–3 requires that a broker-dealer create a record for each account indicating the customer or owner was furnished with a copy of each written agreement entered into on or after the effective date of the rule and that, if requested by the customer or owner, the customer or owner was furnished with a fully executed copy of each agreement. Would an instruction to wire monies out of a customer's account be considered a ''written agreement,'' a copy of which must be provided to the customer pursuant to the new rule?

Answer #6

An instruction received by the broker-dealer from the customer would not constitute a written agreement for purposes of this rule. Examples of written agreements contemplated by this new paragraph would include customer account agreements, margin agreements, options agreements, or securities lending agreements. However, a written instruction sent by the customer to the broker-dealer would constitute a communication received by the broker-dealer relating to its business as such, and should be maintained in accordance with paragraph 17a–4(b)(4).

Question #7, Parts A and B

Background

A broker-dealer may create a team of associated persons to handle business with a particular customer rather than designating one associated person as being responsible for the account. In this situation, no individual team member is directly compensated for a particular transaction; instead, each transaction by that customer is credited to the team for compensation purposes. Consequently, when a member of the team creates an order ticket, the broker-dealer often only records the identity of the team on its order ticket as having entered the order.

Part A

New provisions to paragraphs (a)(6) and (a)(7) of Rule 17a–3 require a broker-dealer to record on the order ticket the identity of the associated person responsible for the account and the identity of the person who entered or accepted the order on behalf of the customer. If a broker-dealer has assigned a team of associated persons to a customer's account, must it record the identity of a particular associated person on the order ticket to meet these new requirements?

Answer #7, Part A

In the Books and Records Release, the Commission stated that a firm may comply with Rule 17a–3(a)(6) and (a)(7) if it records on the order ticket an identification number or code assigned to the person entering or accepting the order or the computer terminal at which an order was entered or accepted, provided that the firm has created and maintained as part of the order ticket records a companion record that can be used to identify the associated person entering the order. Similarly, the broker-dealer may record the identity of the team on the order ticket, provided it creates and maintains a companion record that can be used to identify the associated person that entered that order. The companion record would be part of the firm's order ticket records and must be maintained, preserved, and available for examination in the same manner as the firm's order tickets.

Part B

New Rule 17a–3(a)(19)(i) requires a broker-dealer to create a record, as to each associated person, listing each purchase and sale of a security attributable for compensation purposes to that associated person. If a broker-dealer has created a team of associated persons as described above, must it create a separate duplicate record for each associated person listing each transaction attributed to the team to comply with this rule?

Answer #7, Part B

To comply with Rule 17a–3(a)(19)(i), a broker-dealer that has created a team of associated persons as described above may create a single record that identifies each transaction attributable to a particular team for compensation purposes provided that the firm also creates and maintains as part of this record a companion record that identifies each associated person that has been a member of that team, including the dates the person joined and left the team, and the manner in which compensation is allocated among the members of the team.

Question #8

New Rule 17a–3(a)(19)(i) requires each broker-dealer to create a record as to each associated person listing each purchase and sale of a security attributable, for compensation purposes, to that associated person. The record shall include the amount of compensation if monetary and a

description of the compensation if non-monetary. The Books and Records Release states that:

> The term ''non-monetary compensation'' includes compensation such as sales incentives, gifts, or trips that would be provided to associated persons if certain sales goals were achieved. Such non-monetary compensation should be recorded if directly related to sales. If sales would be counted toward achieving these goals, then a notation of the sales should be made regardless of whether that goal is actually achieved.[6]

Assume the following fact pattern. A broker-dealer with 100 registered representatives, at the end of each year, reviews the sales performance of all of its registered representatives, and sends the five representatives that have generated the most commission revenues for the firm to Hawaii for a week. Under this sales incentive plan, registered representatives do not receive additional credit for earning commissions on any particular product or type of products. The broker-dealer has created a record pursuant to Rule 17a–3(a)(19)(i) for each associated person listing each transaction that contributed to their achievement of this non-monetary compensation because those persons received monetary commissions for each transaction. Would the firm be required under Rule 17a–3(a)(19)(i) to separately note on the record for each associated person the trip to Hawaii as potential compensation?

Answer #8

In this circumstance, a broker-dealer would be in compliance with Rule 17a–3(a)(19)(i) if it created a single record describing the firm's practice of providing an end-of-year non-cash bonus to a certain number of representatives, a description of the non-cash bonus, the criteria used to select which representatives would achieve such a bonus, a list or description of the representatives eligible to receive the bonus, and the names of the registered representatives that received the non-cash bonus.

Question #9

Rule 17a–3(a)(19)(ii) requires that a broker-dealer maintain a record of agreements pertaining to the relationship between each associated person and the broker-dealer, including a summary of each associated person's compensation arrangements such as commission and concession schedules. Some associated persons do not directly participate in securities transactions with customers. One example is an attorney who is an associated person and is compensated based on a fixed salary and a discretionary bonus determined by the firm's management based on the profits of the firm as a whole. Another example would be a branch manager who does not generally receive sales-related compensation, but does receive a bonus if the branch achieves a certain yearly sales goal (for instance, $10 million in annual commissions). Must a broker-dealer create the record required under Rule 17a–3(a)(19)(ii) for the attorney or the branch manager based on the compensation schemes described above where they do not directly participate in securities transactions with customers?

Answer #9

Generally, if an associated person is not directly involved with or compensated based on securities transactions with customers, the broker-dealer would not be required to create the record required pursuant to Rule 17a–3(a)(19)(ii). In the example of the attorney who is compensated based on a salary and discretionary yearly bonus based on the profits of the firm as a whole, the broker-dealer would not be required to create the record required under Rule 17a–3(a)(19)(ii). However, in the example of the branch manager that receives a bonus tied to the yearly sales goal for that branch, the broker-dealer would be required to create the Rule 17a–3(a)(19)(ii) record, even though the branch manager is not directly involved in the customer's securities transactions, because the compensation is intended to reward the branch manager for encouraging sales.

Question #10

New Rule 17a–4(e)(6) requires every broker-dealer to preserve each report that a securities regulatory authority has requested or required the broker-dealer to make and furnish to it pursuant to an order or settlement. Under this rule, is a broker-dealer required to preserve documents or other materials delivered to the Commission in response to a Commission subpoena?

Answer #10

Rule 17a–4(e)(6) does not require a broker-dealer to preserve documents or other materials delivered to the Commission in response to a subpoena. However, if those documents are otherwise required to be created and maintained pursuant to Rules 17a–3 and 17a–4, the broker-dealer must preserve them in compliance with those provisions. In addition, we note that a broker-dealer, under other applicable laws or rules, may have an obligation to preserve such reports, documents or other materials.

Question #11

Rule 17a–3(a)(1) requires that a broker-dealer make and keep current blotters containing, among other things, an itemized daily record of all purchases and sales of securities and all receipts and disbursements of cash. When purchasing a mutual fund, variable annuity, or a direct participation program a broker-dealer's participation in the transaction may be limited to forwarding the customer's completed application and check to the fund. In other purchase transactions, a registered representative may make a recommendation to a customer and assist the customer in completing the purchase application, but the customer may send the application and check to the fund. With relation to sale transactions, the customer may request that the broker-dealer send the sale instruction to the fund on the customer's behalf. Alternatively, the customer may write or call the fund directly and request that the fund sell those shares and the broker-dealer may not be compensated for participating in the sale. In some instances, the purchase of a variable contract would automatically initiate the sale of another variable contract, such as in a 1035 exchange. When must the broker-dealer record these transactions on its purchase and sales blotter?

Answer #11

Under Rule 17a–3(a)(1), a broker-dealer must record all purchases or sales of mutual funds, variable contracts, or direct participation programs. For example, if the broker-dealer forwards an application and check to the fund on behalf of the customer, sends a purchase or sale instruction to the fund (including an instruction resulting in a 1035 exchange), or calls the fund to place an order on behalf of the customer, the transaction must be recorded on the broker-dealer's purchase and sales blotter, regardless of whether the firm received compensation for the transaction. Further, if the broker-dealer forwarded an instruction regarding a 1035 exchange, the firm must record both the relevant sale and purchase transactions on its blotter.

If a customer wrote or talked to the registered representative or if the registered representative helped the customer fill out the subscription agreement but the customer subsequently took that paperwork when departing from the broker-dealer's office, the broker-dealer generally would not be required to record the transaction

[6] 66 FR 55818, at 55823 (November 2, 2001).

on its purchase and sales blotter. However, the broker-dealer may be required to create and maintain other types of records relating to these transactions, for example, pursuant to new paragraph 17a–3(a)(19)(i) and SRO rules.[7]

III. Change to Code of Federal Regulations

List of Subjects in 17 CFR Part 241

Brokers, Reporting and recordkeeping requirements, Securities.

[7] *See e.g.*, NYSE Rule 405 and NASD Rule 3110(c).

Amendments to the Code of Federal Regulations

■ For the reasons set out in the preamble, title 17 chapter II of the Code of Federal Regulations is amended as set forth below:

PART 241—INTERPRETIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

■ Part 241 is amended by adding Release No 34–47910 and the release date of May 22, 2003 to the list of interpretive releases.

By the Commission.

Dated: May 22, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–13444 Filed 5–28–03; 8:45 am]

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Thursday,
May 29, 2003

Part VI

The President

Executive Order 13304—Termination of Emergencies With Respect to Yugoslavia and Modification of Executive Order 13219 of June 26, 2001

Federal Register
Vol. 68, No. 103
Thursday, May 29, 2003

Presidential Documents

Title 3—

The President

Executive Order 13304 of May 28, 2003

Termination of Emergencies With Respect to Yugoslavia and Modification of Executive Order 13219 of June 26, 2001

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act, as amended (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), section 5 of the United Nations Participation Act of 1945, as amended (22 U.S.C. 287c) (UNPA), and section 301 of title 3, United States Code,

I, GEORGE W. BUSH, President of the United States of America, have determined that the situations that gave rise to the declarations of national emergencies in Executive Order 12808 of May 30, 1992, and Executive Order 13088 of June 9, 1998, with respect to the former Socialist Federal Republic of Yugoslavia, have been significantly altered by the peaceful transition to democracy and other positive developments in Serbia and Montenegro (formerly the Federal Republic of Yugoslavia (Serbia and Montenegro)). Accordingly, I hereby terminate the national emergencies declared in those orders and revoke those and all related orders (Executive Orders 12810 of June 5, 1992, 12831 of January 15, 1993, 12846 of April 25, 1993, 12934 of October 25, 1994, 13121 of April 30, 1999, and 13192 of January 17, 2001). At the same time, and in order to take additional steps with respect to continuing, widespread, and illicit actions that obstruct implementation of the Ohrid Framework Agreement of 2001, relating to Macedonia, United Nations Security Council Resolution 1244 of June 10, 1999, relating to Kosovo, or the Dayton Accords or the Conclusions of the Peace Implementation Conference Council held in London on December 8–9, 1995, including the decisions or conclusions of the High Representative, the Peace Implementation Council or its Steering Board, relating to Bosnia and Herzegovina, including the harboring of individuals indicted by the International Criminal Tribunal for the former Yugoslavia, and the national emergency described and declared in Executive Order 13219 of June 26, 2001, I hereby order:

Section 1. Pursuant to section 202 of the NEA (50 U.S.C. 1622), termination of the national emergencies declared in Executive Order 12808 of May 30, 1992, and Executive Order 13088 of June 9, 1998, shall not affect any action taken or proceeding pending not finally concluded or determined as of the effective date of this order, or any action or proceeding based on any act committed prior to such date, or any rights or duties that matured or penalties that were incurred prior to such date. Pursuant to section 207 of IEEPA (50 U.S.C. 1706), I hereby determine that the continuation of prohibitions with regard to transactions involving any property blocked pursuant to Executive Orders 12808 or 13088 that continues to be blocked as of the effective date of this order is necessary on account of claims involving successor states to the former Socialist Federal Republic of Yugoslavia or other potential claimants.

Sec. 2. The Annex to Executive Order 13219 of June 26, 2001, is replaced and superseded in its entirety by the Annex to this order.

Sec. 3. (a) Section 1(a) and 1(b) of Executive Order 13219 are revised to read as follows:

''**Section 1.** (a) Except to the extent provided in section 203(b)(1), (3), and (4) of IEEPA (50 U.S.C. 1702(b)(1), (3), and (4)), and the Trade Sanctions Reform and Export Enhancement Act of 2000 (Title IX, Public Law 106–

387), and in regulations, orders, directives, or licenses that may hereafter be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted prior to the effective date of this order, all property and interests in property of:

(i) the persons listed in the Annex to this order; and

(ii) persons designated by the Secretary of the Treasury, in consultation with the Secretary of State, because they are determined:

(A) to be under open indictment by the International Criminal Tribunal for the former Yugoslavia, unless circumstances warrant otherwise, or

(B) to have committed, or to pose a significant risk of committing, acts of violence that have the purpose or effect of threatening the peace in or diminishing the stability or security of any area or state in the Western Balkans region, undermining the authority, efforts, or objectives of international organizations or entities present in the region, or endangering the safety of persons participating in or providing support to the activities of those international organizations or entities, or

(C) to have actively obstructed, or pose a significant risk of actively obstructing, the Ohrid Framework Agreement of 2001 relating to Macedonia, United Nations Security Council Resolution 1244 relating to Kosovo, or the Dayton Accords or the Conclusions of the Peace Implementation Conference held in London on December 8–9, 1995, including the decisions or conclusions of the High Representative, the Peace Implementation Council or its Steering Board, relating to Bosnia and Herzegovina, or

(D) to have materially assisted in, sponsored, or provided financial, material, or technological support for, or goods or services in support of, such acts of violence or obstructionism or any person listed in or designated pursuant to this order, or

(E) to be owned or controlled by, or acting or purporting to act directly or indirectly for or on behalf of, any person listed in or designated pursuant to this order, that are or hereafter come within the United States, or that are or hereafter come within the possession or control of United States persons, are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

(b) I hereby determine that the making of donations of the type specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by or to persons determined to be subject to the sanctions imposed under this order would seriously impair the ability to deal with the national emergency declared in this order, and hereby prohibit such donations as provided in paragraph (a) of this section.''

Sec. 4. New sections 7 and 8 are added to Executive Order 13219 to read as follows:

''**Sec. 7.** For those persons listed in the Annex to this order or determined to be subject to the sanctions imposed under this order who might have a constitutional presence in the United States, I have determined that, because of the ability to transfer funds or assets instantaneously, prior notice to such persons of measures to be taken pursuant to this order would render these measures ineffectual. I therefore determine that for these measures to be effective in addressing the national emergency declared in this order, there need be no prior notice of a listing or determination made pursuant to this order.

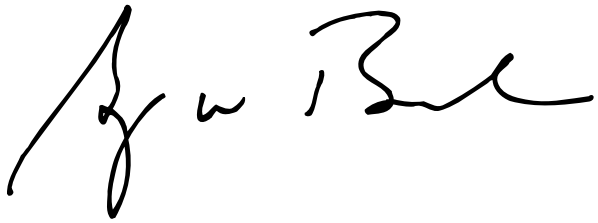
Sec. 8. The Secretary of the Treasury, in consultation with the Secretary of State, is authorized to determine, subsequent to the issuance of this order, that circumstances no longer warrant inclusion of a person in the Annex to this order and that such person is therefore no longer covered within the scope of the sanctions set forth herein. Such a determination shall become effective upon publication in the **Federal Register**.''

Sec. 5. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including the promulgation

of rules and regulations, and to employ all powers granted to the President by IEEPA and UNPA, as may be necessary to carry out the purposes of this order. The Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the United States Government. All agencies of the United States Government are hereby directed to take all appropriate measures within their authority to carry out the provisions of this order and, where appropriate, to advise the Secretary of the Treasury in a timely manner of the measures taken.

Sec. 6. Nothing contained in this order shall create any right or benefit or privilege, substantive or procedural, enforceable at law or in equity by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 7. This order is effective at 12:01 a.m. eastern daylight time on May 29, 2003. This order shall be transmitted to the Congress and published in the **Federal Register**.



THE WHITE HOUSE,

May 28, 2003.

Billing code 3195–01–P

ANNEX

Ademi, Rahim [born 30 Jan 1954 Karac, SaM; ICTY indictee]
Ademi, Xhevat [born 8 Dec 1962 Tetovo, MK]
Adili, Gafur [born 5 Jan 1959 Kicevo, MK]
Albanian National Army (ANA, a.k.a. AKSh)
Alispahic, Bakir [born 1 Oct 1956, Ahatovici, BiH]
Army of the Republic of Ilirida (ARI)
Arsenovic, Djojo [born 6 Jan 1952, Donje Crnjelovo, BiH]
Bajagic, Zvonko "Duga Puska" [born 6 Sep 1953, Vlasenica, BiH]
Bala, Haradin [born 10 Jun 1957 Gornja Koretica, SaM; ICTY indictee]
Banovic, Predrag [born 28 Oct 1969 Prijedor, BiH; ICTY indictee]
Beqiri, Idajet (Hidajet) [born 20 Feb 1951 Mallakaster Fier, Albania]
Bexheti, Nuri [born 1962 Tetovo, MK]
BIO Corporation (aka, Bosnian Investment Organization), Sarajevo, BiH
Bjelica, Milovan "Cicko" [born19 Oct 1958, Rogatica, BiH, National ID No. 1910958130007]
Blagojevic, Vidoje [born 22 Jun 1950 Bratunac, BiH; ICTY indictee]
Blaskic, Tihomir [born 2 Nov 1960 Brestovsko, BiH; ICTY indictee]
Borovcanin, Ljubomir [born 27 Feb 1960, Han Pijesak, BiH; ICTY indictee]
Borovnica, Goran [born 15 Aug 1965; ICTY indictee]
Boskovski, Ljube [born 24 Oct 1960]
Brdjanin, Radoslav [born 9 Feb 1948 Popovac, BiH; ICTY indictee]
Butka, Spiro [born 29 May 1949]
Cengic, Hasan [born 3 Aug 1957, Odzak, BiH]
Cerkez, Mario [born 27 Mar 1959 Rijeka, BiH; ICTY indictee]
Cesic, Ranko [born 5 Sep 1964 Drvar, BiH; ICTY indictee]
Cesic-Rojs, Ljubo [born 20 Feb 1958, Posulje, BiH]
Cetnik Ravnagorski Pokret (CRP)
Coric, Valentin [born 23 Jun 1956, Citluk, BiH]
Dalipi, Tahir [born 1958 Ilince, SaM]
Delic, Hazim [born 13 May 1964; ICTY indictee]
Deronjic, Miroslav [born 6 June 1945 Bratunac, BiH; ICTY indictee]
Djogo, Jovan [born Kalinovik, BiH]
Dosen, Damir [born 7 Apr 1967 Cirkin Polje, BiH; ICTY indictee]
Elshani, Gafur [born 29 Mar 1958 Suva Reka, SaM]
Front for Albanian National Unity (FBKSh)
Furundzija, Anto [born 8 Jul 1969 Travnik, BiH; ICTY indictee]
Fustar, Dusan [born 29 Jun 1954 Prijedor, BiH; ICTY indictee]
Gajic-Milosevic, Milica [born 1970 Milosevic Family]

Galic, Stanislav [born 12 Mar 1943 Goles, BiH; ICTY indictee]
Gashi, Sabit [born 30 Dec 1967 Suva Reka, SaM]
Gotovina, Ante [born 12 Oct 1955 Pasman, HR; ICTY indictee]
Gruban, Momcilo [born 19 Jun 1961 Bosnian Serb; ICTY indictee]
Habibi, Skender [born 13 Jul 1968 Vitina, SaM]
Hadzihasanovic, Enver [born 7 Jul 1950 Zvornik, BiH; ICTY indictee]
Halili, Nevzat [born 15 Sep 1946 Poroj, MK]
Halilovic, Sefer [born 6 Jan 1952 Prijepolje, SaM; ICTY indictee]
Haradinaj, Daut [born 6 Apr 1978 Glodjane, SaM]
Hasani, Zhavit [born 5 May 1957 Tanusevci, MK]
Haxhirexha, Kastriot [born 9 May 1961 Debar, MK]
Hyseni, Xhemajl [born 15 Aug 1958 Lojane, MK]
Ivanovic, Milan [born 5 Feb 1955]
Jaksic, Marko [born 1954 Mitrovica, SaM]
Jankovic, Gojko [born 31 Oct 1954 Foca, BiH; ICTY indictee]
Jelavic, Ante [born 21 Oct 1963, Potprolog, HR]
Jelisic, Goran [born 7 Jun 1968 Bijeljina, BiH; ICTY indictee]
Jokic, Dragan [born 20 Aug 1957 Grbavci, BiH; ICTY indictee]
Jokic, Miodrag [born 1935 Mionica, SaM; ICTY indictee]
Josipovic, Drago [born 14 Feb 1955 Santici, BiH; ICTY indictee]
Karadzic, Aleksandar "Sasa" [born 14 May 1973, Sarajevo, BiH]
Karadzic, Luka [born 31 Apr 1951, Savnik, SaM]
Karadzic, Radovan [born 19 Jun 1945 Petnica, SaM; ICTY indictee]
Karadzic-Jovicevic, Sonja [born 22 May 1967, Sarajevo, BiH]
Knezevic, Dusan [born 23 Jun 1955 Orlovci, BiH; ICTY indictee]
Kordic, Dario [born 14 Dec 1960 Sarajevo, BiH; ICTY indictee]
Kos, Milojica [born 1 April 1963 Lamovita, BiH; ICTY indictee]
Kovacevic, Vladimir [born 15 Jan 1961; ICTY indictee]
Krajisnik, Momcilo [born 20 Jan 1945 Zabrdje, BiH; ICTY indictee]
Krnojelac, Milorad [born 25 Jul 1940 Birotici, BiH; ICTY indictee]
Krstic, Radislav [born 15 Feb 1948, Nedjeljiste, Vlasenica, BiH; ICTY indictee]
Kryeziu, Izmet [born 3 Oct 1954 Pagarusha-Malishev, SaM]
Kubura, Amir [born 4 Mar 1964 Kakanj, BiH;; ICTY indictee]
Kunarac, Dragoljub [born 15 May 1960 Foca, BiH;; ICTY indictee]
Kvocka, Miroslav [born 1 Jan 1957 Maricka, BiH; ICTY indictee]
Lalovic, Dragan "Mate" [born 14 Jun 1953, Vlaholje, nr. Kalinovik, BiH]
Landzo, Esad [born 7 Mar 1973; ICTY indictee]
Liberation Army of Presevo, Medvedja, and Bujanovac (UCPMB)
Limaj, Fatmir [born 4 Feb 1971 Banja, SaM; ICTY indictee]
Ljubicic, Pasko [born 15 Nov 1965 Nezirovic, BiH; ICTY indictee]
Lladrovici, Ramiz [born 3 Jan 1966]

Lukic, Milan [born 6 Sep 1967 Foca, BiH; ICTY indictee]
Lukic, Sredoje [born 5 Apr 1961 Visegrad, BiH; ICTY indictee]
Lukovic, Milorad Ulemek "Legija" [born 15 Mar 1968 Belgrade, SaM]
Lushtaku, Sami [born 20 Feb 1961 Srbica, SaM]
Manco Oil Company
Mandic, Momcilo "Momo" [born 1 May 1954, Kalinovik, BiH; National ID no. JMB 0105954171511]
Marinic, Zoran [born 6 Jun 1963 Busovaca, BiH; ICTY indictee]
Markovic, Mirjana [born 10 Jul 1942; wife of Slobodan Milosevic]
Markovic, Radovac [born 1946 or 1947 Ex-FRY Deputy Minister of Interior]
Marku, Ton [born 13 Jun 1964]
Martic, Milan [born 18 Nov 1954 Zagrovic, HR; ICTY indictee]
Martinovic, Vinko [born 21 Sep 1963 Mostar, BiH; ICTY indictee]
Mejakic, Zeljko [born 2 Aug 1964 Petrov Gaj, BiH; ICTY indictee]
Milosevic, Borislav [born 1936 Milosevic Family]
Milosevic, Dragomir [born 4 Feb 1942 Murgas, BiH; ICTY indictee]
Milosevic, Marija [born 1965; Milosevic Family]
Milosevic, Marko [born 2 Jul 1974; son of Slobodan Milosevic]
Milosevic, Milanka [Milosevic Family]
Milosevic, Slobodan [born 20 Aug 1941 Pozarevac, SaM ex-FRY President; ICTY indictee]
Milutinovic, Milan [born 19 Dec 1942 Belgrade, SaM; ex-Pres. of Republika Srpska; ICTY indictee]
Mladic, Ratko [born 12 Mar 1943 Bozinovici, BiH; ICTY indictee]
Morina, Xhavit [born 13 Sep 1963 Drenovc]
Mrdja, Darko [born 28 Jun 1967 Zagreb, HR; ICTY indictee]
Mrksic, Milan [born 20 Jul 1947 Vrginmost, HR; ICTY indictee]
Mucic, Zdravko [born 31 Aug 1955; ICTY indictee]
Musliu, Isak [born 31 Oct 1970 Racak, SaM]
Musliu, Jonuz [born 5 Jan 1959 Konculj, SaM]
Musliu, Shefqet [born 12 Feb 1963 Konculj, SaM]
Mustafa, Rrustem [born 27 Feb 1971 Podujevo, SaM]
Naletilic, Mladen [born 1 Dec 1946 Listica, BiH; ICTY indictee]
National Committee for the Liberation and Protection of Albanian Lands (KKCMTsh)
National Liberation Army (NLA, a.k.a. UCK)
National Movement for the Liberation of Kosovo (LKCK)
Ndrecaj, Maliq [born 22 Apr 1969 Maciteve, SaM]
Nikolic, Dragan [born 26 Apr 1957 Vlasenica, BiH; ICTY indictee]
Nikolic, Drago [born 9 Nov 1957 Vlasenica, BiH; ICTY indictee]
Nikolic, Momir [born 20 Feb 1955 Bratunac, BiH; ICTY indictee]
Nikolic, Zarko [born 7 May 1938, Sovljak, SaM]
Obrenovic, Dragan [born 12 Apr 1963 Matino Brdo, BiH; ICTY indictee]

Ojdanic, Dragoljub [born 1 Jun 1941 Ravni-Cajetina, SaM; Ex-Fry Minister of Defense; ICTY indictee]
Oric, Naser [born 3 March 1967, Potocari, BiH; ICTY indictee]
Pandurevic, Vinko [born 1959 Sokolac, BiH; ICTY indictee]
Pavkovic, Nebojsa [born 10/16 Apr 1946 Senjski Rudnik, SaM Ex-VJ Chief of Staff]
Peric, Jozo "Tukesa" [born 31 Jan 1959, Pjesevac Kula, BiH]
Plavsic, Biljana [born 7 Jul 1930 Tuzla, BiH; ICTY indictee]
Political Council of Presevo, Medvedja, and Bujanovac (PCPMB)
Popovic, Vujadin [born 14 Mar 1957; ICTY indictee]
Popular Movement of Kosovo (LPK)
Prcac, Dragoljub [born 18 Jul 1937 Omarska, BiH; ICTY indictee]
PRIVREDNA BANKA AD SRPSKO SARAJEVO (a.k.a. PRIVREDNA BANKA SARAJEVO AD), Str Srpskih Ratnika br 14, 71420 Pale, Republika Srpska, Bosnia-Herzegovina; Dobroslava Jedevica 14, 71000 Pale, Republika Srpska, Bosnia-Herzegovina; Kralja Nikole Str 65, Srbinje/Foca, Republika Srpska, Bosnia-Herzegovina; Ljube Milanovica Str 12, Trebinje, Republika Srpska, Bosnia-Herzegovina; Filipa Kljajica Str 6, Zvornik, Republika Srpska, Bosnia-Herzegovina; 9/11 Str Zagrebacka, Belgrade11000, Serbia
PRIVREDNA BANKA SARAJEVO AD (a.k.a. PRIVREDNA BANKA AD SRPSKO SARAJEVO), Str Srpskih Ratnika br 14, 71420 Pale, Republika Srpska, Bosnia-Herzegovina; Dobroslava Jedevica 14, 71000 Pale, Republika Srpska, Bosnia-Herzegovina; Kralja Nikole Str 65, Srbinje/Foca, Republika Srpska, Bosnia-Herzegovina; Ljube Milanovica Str 12, Trebinje, Republika Srpska, Bosnia-Herzegovina; Filipa Kljajica Str 6, Zvornik, Republika Srpska, Bosnia-Herzegovina; 9/11 Str Zagrebacka, Belgrade11000, Serbia
Puma Security Company (aka Puma Security Service, aka Puma Security Agency), Mostar, Capljina, Stolac, and Siroki Brijeg, BiH
Radic, Miroslav [born 1 Jan 1961; ICTY indictee]
Radic, Mlado [born 15 May 1952 Lamovita, BiH; ICTY indictee]
Rajic, Ivica [born 5 May 1958 Johovac, BiH; ICTY indictee]
Rasevic, Mitar [born 1940 Cagust, BiH; ICTY indictee]
Rexhepi, Daut [born 1962 Poroj, MK]
Roguljic, Slavko [born c. 1952]
Rushiti (Ruxheti), Sait [born 7 Nov 1966]
Sahinpasic, Senad [born c. 1951, Foca, BiH]
Sainovic, Nikola [born 7 Dec 1948 Bor, SaM; Ex-FRY Deputy Prime Minister; ICTY indictee]
Samiu, Izair [born 23 Jul 1963]
Santic, Vladimir [born 1 Apr 1958 Donja Veceriska, BiH; ICTY indictee]
Selimi, Rexhep [born 15 Mar 1971 Iglarevo, SaM]
Seselj, Vojislav [born 11 Oct 1954 Sarajevo, BiH; ICTY indictee]

Shaqiri, Shaqir [born 1 Sep 1964 SaM]
Sikirica, Dusko [born 23 Mar 1964 Cirkin Pojle, BiH; ICTY indictee]
Simatovic, Franko "Frenki" [born 1 April 1950 Belgrade, SaM, ICTY indictee]
Simic, Blagoje [born 1 Jul 1960 Kruskovo Polje; ICTY indictee]
Simic, Milan [born 9 Aug 1960 Sarajevo, BiH; ICTY indictee]
Sljivancanin, Veselin [born 13 Jun 1953 Zabljak, SaM; ICTY indictee]
Sopta, Stanko [born 4 Feb 1966, Duzice, BiH]
Stakic, Milomir [born 19 Jun 1962 Maricka, BiH; ICTY indictee]
Stanisic, Jovica [born 30 July 1950 Ratkovo, SaM, ICTY indictee]
Stankovic, Radovan [born 10 Mar 1953 Trebica, BiH; ICTY indictee]
Stepanovic, Novak [born 25 Apr 1966, Srebrenica, BiH]
Strugar, Pavle [born 13 Jul 1933 Pec, SaM; ICTY indictee]
Subotic, Bogdan [born 25 April 1941, Bosanska Gradiska, BiH]
Suma, Emrush [born 27 May 1974 Dimce, SaM]
Syla, Azem [born 5 Apr 1951 SaM]
Tadic, Dusan, aka "Dusko" aka "Dule" [born 1956, Cajnice, BiH; ICTY indictee]
Tadic, Miroslav [born 12 May 1937 Novi Grad, BiH; ICTY indictee]
Talic, Momir [born 15 Jul 1942 Piskavica, BiH; ICTY indictee]
Todorovic, Stevan [born 29 Dec 1957 Donja Slatina, BiH; ICTY indictee]
Todovic, Savo [born 11 Dec 1952 Rijeka, BiH; ICTY indictee]
Uksini (Ukshini), Sami [born 5 Mar 1963 Gjakova, SaM]
Vasiljevic, Mitar [born 25 Aug 1954 Durevici, BiH; ICTY indictee]
Vukovic, Zoran [born 6 Sep 1955 Brusna, BiH; ICTY indictee]
Xhaferi, Shefit [born 1960]
Xhemajli, Emrush [born 5 May 1959 Urosevac, SaM]
Xhemajli, Muhamet [born 8 Feb 1958 Muhovac, SaM]
Zaric, Simo [born 25 Jul 1948 Trnjak, BiH; ICTY indictee]
Zelen-Karadzic, Ljiljana [born 27 Nov 1945, Sarajevo BiH]
Zelenovic, Dragan [born 12 Feb 1961; ICTY indictee]
Zigic, Zoran [born 20 Sep 1958 Balte, BiH; ICTY indictee]
Zupljanin, Stojan [born 1951 Maslovare, BiH; ICTY indictee]

Note: The bracketed identifying information with respect to each person listed in this Annex reflects information currently available and is provided solely to facilitate compliance with this order. Each individual listed in this Annex remains subject to the prohibitions of this order notwithstanding any change in title, position, or affiliation.

[FR Doc. 03–13694

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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H.J. Res. 51/P.L. 108–24

Increasing the statutory limit on the public debt. (May 27, 2003; 117 Stat. 710)

H.R. 1298/P.L. 108–25

United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (May 27, 2003; 117 Stat. 711)

H.R. 2185/P.L. 108–26

Unemployment Compensation Amendments of 2003 (May 28, 2003; 117 Stat. 751)

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